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9
10 **UNITED STATES DISTRICT COURT**
11 **CENTRAL DISTRICT OF CALIFORNIA**

12
13 MANH HO, derivatively on behalf of
14 EDWARDS LIFESCIENCES
15 CORPORATION,

16 Plaintiff,

17 v.
18 BERNARD J. ZOVIGHIAN, LARRY L.
19 WOOD, SCOTT B. ULLEM, LESLIE C.
20 DAVIS, KIERAN T. GALLAHUE,
21 LESLIE S. HEISZ, PAUL A.
22 LAVIOLETTE, STEVEN R.
23 LORANGER, MARTHA H. MARSH,
24 MICHAEL A. MUSSALLEM,
25 RAMONA SEQUEIRA, AND
26 NICHOLAS J. VALERIANI,

27 Defendants,

28 and
EDWARDS LIFESCIENCES
CORPORATION,

Case No.:

DEMAND FOR JURY TRIAL

VERIFIED SHAREHOLDER
DERIVATIVE COMPLAINT

Nominal Defendant.

1

2

3 **INTRODUCTION**

4 Plaintiff Manh Ho (“Plaintiff”), by Plaintiff’s undersigned attorneys, derivatively
5 and on behalf of nominal defendant Edwards Lifesciences Corporation (“Edwards” or the
6 “Company”), files this Verified Shareholder Derivative Complaint against defendants
7 Bernard T. Zovighian (“Zovighian”), Larry L. Wood (“Wood”), Scott B. Ullem (“Ullem”),
8 Leslie C. Davis (“Davis”), Kieran T. Gallahue (“Gallahue”), Leslie S. Heisz (“Heisz”),
9 Paul A. LaViolette (“LaViolette”), Steven R. Loranger (“Loranger”), Martha H. Marsh
10 (“Marsh”), Michael A. Mussallem (“Mussallem”), Ramona Sequeira (“Sequeira”), and
11 Nicholas J. Valeriani (“Valeriani”) (collectively, the “Individual Defendants,” and together
12 with Edwards, “Defendants”) for breaches of their fiduciary duties as directors and/or
13 officers of Edwards, unjust enrichment, abuse of control, gross mismanagement, waste of
14 corporate assets, for violations of Sections 14(a), 10(b), and 20(a) of the Securities
15 Exchange Act of 1934 (the “Exchange Act”), and against Defendants Zovighian, Wood,
16 and Ullem for contribution under Sections 10(b) and 21D of the Exchange Act. As for
17 Plaintiff’s complaint against the Individual Defendants, Plaintiff alleges the following
18 based upon personal knowledge as to Plaintiff and Plaintiff’s own acts, and information
19 and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and
20 through Plaintiff’s attorneys, which included, among other things, a review of the
21 Defendants’ public documents, conference calls and announcements made by Defendants,
22 United States Securities and Exchange Commission (“SEC”) filings, wire and press
23 releases published by and regarding Edwards, legal filings, news reports, securities
24 analysts’ reports and advisories about the Company, and information readily obtainable on
25 the Internet. Plaintiff believes that substantial evidentiary support will exist for the
26 allegations set forth herein after a reasonable opportunity for discovery.

27 **NATURE OF THE ACTION**

28 1. This is a shareholder derivative action that seeks to remedy wrongdoing

1 committed by the Individual Defendants from February 6, 2024 and July 24, 2024,
2 inclusive (the “Relevant Period”).

3 2. Edwards is a medical sciences corporation that specializes in creating medical
4 devices to assist with the treatment of structural heart disease and critical care monitoring.
5 For over sixty years, the Company has become a pioneer in the development of heart valve
6 therapies.

7 3. Among these therapies is the Company’s core product, the Transcatheter
8 Aortic Valve Replacement (“TAVR”).

9 4. The Relevant Period began on February 6, 2024 when the Company issued a
10 press release announcing the Company’s financial results (the “FY 2023 Earnings
11 Release”) for the fourth quarter and year-end of the fiscal year ended December 31, 2023
12 (the “2023 Fiscal Year”). The FY 2023 Earnings Release went into the Company’s TAVR
13 sales, which “grew 13 percent” in the fourth quarter of the 2023 Fiscal Year. Further, the
14 FY 2023 Earnings Release highlighted that the Company’s “constant currency sales grew
15 12 percent.” In discussing the results, the FY 2023 Earnings Release quoted Defendant
16 Zovighian as stating that:

17 In 2023, our team made significant progress advancing transformational
18 therapies for patients while delivering strong financial performance. Full year
19 sales increased 12 percent, including impressive growth across each of our
20 four product groups. We exited the year with strong momentum driven by our
21 broad portfolio of innovative therapies. In 2024, we anticipate launching
22 multiple breakthrough technologies globally and advancing important clinical
23 trials as we embark on a new era of structural heart innovation. These
24 breakthroughs, along with significant unmet patient needs, give us confidence
25 in our ability to accelerate growth in 2025 and beyond.

26 5. Throughout the Relevant Period, the Individual Defendants consistently
27 issued these positive statements to investors despite the fact that the Company’s claims
28 were too reliant on their ability to entice members of the low-treatment-rate population of
patients, as well as an overestimation in hospitals’ and other care facilities’ will to continue

1 utilizing and committing resources to TAVR procedures as opposed to newer, innovative
2 alternatives.

3 6. The truth emerged on July 24, 2024 when the Company issued a press release
4 (the “Q2 2024 Earnings Release”) announcing its financial results for the second quarter
5 of the Fiscal Year ended December 31, 2024 (the “2024 Fiscal Year”). The Q2 2024
6 Earnings Release revealed below-expectation results, namely that the Company slashed its
7 full-year revenue guidance for the TAVR platform. In explaining the negative guidance,
8 the Q2 2024 Earnings Release explained that it was the result of “continued growth and
9 expansion of structural heart therapies … [which] put pressure on hospital workflows.” In
10 essence, despite the Company’s claims, developments in new procedures, including the
11 Company’s Transcatheter Mitral and Tricuspid Therapies (“TMTT”), were putting strain
12 on hospital teams that caused hospitals to under-utilize TAVR.

13 7. On this news, the Company’s stock price fell \$27.25 per share, or 31.3%, from
14 a closing price of \$86.95 per share on July 24, 2024 to close at \$59.70 per share on July
15 25, 2024.

16 8. During the Relevant Period, the Individual Defendants breached their
17 fiduciary duties by personally making and/or causing the Company to make to the investing
18 public a series of materially false and misleading statements regarding the Company’s
19 business, operations, and prospects. Specifically, the Individual Defendants willfully or
20 recklessly made and/or caused the Company to make false and misleading statements that
21 failed to disclose, *inter alia*, that: (1) the Individual Defendants indicated they had reliable
22 information regarding the Company’s projected revenue and anticipated growth; (2) in so
23 doing, the Individual Defendants underplayed the risks associated with seasonality and
24 macroeconomic fluctuations; (3) the Individual Defendants’ model relied too heavily or
25 otherwise overemphasized hospitals’ desires to continue utilizing TAVR over newer, more
26 innovative therapies; (4) as a result, there was a significant risk that TAVR’s growth would
27 decelerate; (5) the Individual Defendants were improperly interested in increasing their
28

1 future compensation by seeking shareholder approval of an Amended Long-Term Stock
2 Incentive Plan (the “2024 Amended Stock Plan”); and (6) the Company lacked internal
3 controls. As a result of the foregoing, the Company’s public statements were materially
4 false and misleading and/or lacked a reasonable basis at all relevant times.

5 9. The Individual Defendants failed to correct and/or caused the Company to fail
6 to correct these false and misleading statements and omissions of material fact, rendering
7 them personally liable to the Company for breaching their fiduciary duties.

8 10. In addition, during the Relevant Period, the Individual Defendants breached
9 their fiduciary duties by causing Edwards to repurchase its own stock at prices that were
10 artificially inflated due to the foregoing misrepresentations. Indeed, between April 2024
11 and July 2024, approximately 2.2 million shares of Edwards common stock were
12 repurchased at artificially inflated prices, costing the Company approximately \$178
13 million. As the Company’s stock was actually worth only \$59.70 per share, the price at
14 which it was trading when markets closed on July 25, 2024, the Company overpaid for
15 repurchases of its own stock by approximately \$48.2 million in total.

16 11. Additionally, in breach of their fiduciary duties, the Individual Defendants
17 willfully or recklessly caused the Company to fail to maintain adequate internal controls
18 while five of the Individual Defendants engaged in improper insider sales, netting total
19 proceeds of ***approximately \$12.3 million.***

20 12. The Company has been substantially damaged as a result of the Individual
21 Defendants’ knowing or highly reckless breaches of fiduciary duty and other misconduct.

22 13. In light of the Individual Defendants’ misconduct—which has subjected the
23 Company, its Chief Executive Officer (“CEO”), its Corporate Vice President and Group
24 President of TAVR and Surgical Structural Heart Therapies, and its Corporate Vice
25 President and Chief Financial Officer (“CFO”) to a federal securities fraud class action
26 lawsuit pending in the United States District Court for the Central District of California
27 (the “Securities Class Action”), and which has further subjected the Company to the need
28

1 to undertake internal investigations, the need to implement adequate internal controls,
2 losses from the waste of corporate assets, and losses due to the unjust enrichment of the
3 Individual Defendants who were improperly overcompensated by the Company and/or
4 who benefitted from the wrongdoing alleged herein—the Company will have to expend
5 many millions of dollars.

6 14. The Company has been substantially damaged as a result of the Individual
7 Defendants' knowing or highly reckless breaches of fiduciary duty and other misconduct.

8 15. In light of the breaches of fiduciary duty engaged in by the Individual
9 Defendants, most of whom are the Company's current directors, of the collective
10 engagement in fraud and misconduct by the Company's directors, of the substantial
11 likelihood of the directors' liability in this derivative action and of Defendant Zovighian's,
12 Defendant Wood's, and Defendant Ullem's liability in the Securities Class Action, and of
13 their not being disinterested and/or independent directors, a majority of the Company's
14 Board of Directors (the "Board") cannot consider a demand to commence litigation against
15 themselves on behalf of the Company with the requisite level of disinterestedness and
16 independence.

17 **JURISDICTION AND VENUE**

18 16. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331
19 because Plaintiff's claims raise a federal question under Section 14(a) of the Exchange Act,
20 15 U.S.C. § 78n(a)(1), Rule 14a-9 of the Exchange Act, 17 C.F.R. § 240.14a-9, Sections
21 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b), 78t(a) and 78t-1), and SEC Rule
22 10b-5 (17 C.F.R. § 240.10b-5) promulgated thereunder, and Section 21D of the Exchange
23 Act (15 U.S.C. § 78u-4(f)). Plaintiff's claims also raise a federal question pertaining to the
24 claims made in the Securities Class Action based on violations of the Exchange Act.

25 17. This Court has supplemental jurisdiction over Plaintiff's state law claims
26 pursuant to 28 U.S.C. § 1337(a).

27 18. This derivative action is not a collusive action to confer jurisdiction on a court

1 of the United States that it would not otherwise have.
2

3 19. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1401
4 because a substantial portion of the transactions and wrongs complained of herein occurred
5 in this District, one or more of the Defendants either resides or maintains executive offices
6 in this District, Defendants have conducted business in this District, Defendants' actions
7 have had an effect in this District, and Edwards is headquartered in this District.
8

PARTIES

Plaintiff

9 20. Plaintiff is a current shareholder of Edwards. Plaintiff has continuously held
10 Edwards common stock since first purchasing on December 23, 2014.
11

Nominal Defendant Edwards

12 21. Edwards is a Delaware corporation with principal executive offices at One
13 Edwards Way, Irvine, California, 92614. Edwards's common stock trades on the New York
14 Stock Exchange ("NYSE") under the ticker symbol "EW."
15

Defendant Zovighian

16 22. Defendant Zovighian has served as Edwards's CEO and as a Company
17 director since May 2023. Defendant Zovighian has been at the Company since 2015, most
18 recently working as Corporate Vice President and General Manager for TMTT from 2018
19 until becoming CEO. According to the Schedule 14A the Company filed with the SEC on
20 March 26, 2024 (the "2024 Proxy Statement"), as of January 31, 2024, Defendant
21 Zovighian beneficially owned 145,460 shares of the Company's common stock.¹ Given
22 that the price per share of the Company's common stock at the close of trading on January
23 31, 2024 was \$78.47, Defendant Zovighian owned approximately \$11.4 million worth of
24 Edwards stock as of that date.
25
26

27 ¹ The Company calculates its total shares beneficially owned as the sum of its outstanding
28 shares beneficially owned and the total restricted stock units and shares underlying
options.

1 23. During the Relevant Period, while the Company's stock price was artificially
2 inflated and before the scheme was exposed, Defendant Zovighian made the following sale
3 of Company common stock:

Date	Number of Shares	Avg. Price/Share (\$)	Proceeds (\$)
May 30, 2024	8,617	\$87.68	\$755,538

7 Thus, in total, before the fraud was exposed, Defendant Zovighian sold 8,617 shares of
8 Company stock on inside information, for which he received approximately \$755,538 in
9 total proceeds. His insider sale, made with knowledge of material nonpublic information
10 before the material misstatements and omissions were exposed, demonstrate his motive in
11 facilitating and participating in the scheme.

12 24. The 2024 Proxy Statement stated the following about Defendant Zovighian:

13 With a career spanning nearly three decades in medical technology, Mr.
14 Zovighian has led global businesses across two world-class companies during
15 which time he lived and led teams in several countries. Mr. Zovighian blends
16 a global mindset and a team-based approach to leadership with strengths in
17 strategy development, innovation and adoption of disruptive technologies that
18 elevate the standard of care, and establishment of trusted partnerships.

19 Mr. Zovighian joined Edwards Lifesciences in January 2015 as vice president
20 and general manager of the Surgical Structural Heart business, and he later
21 served as corporate vice president of the surgical business from 2016 until he
22 became corporate vice president responsible for the company's Transcatheter
23 Mitral and Tricuspid Therapies (TMTT) business in January 2018. Mr.
24 Zovighian established a global organization focused on developing a portfolio
25 of therapies designed to change the standard of care for mitral and tricuspid
26 patients. Prior to joining Edwards, Mr. Zovighian held roles with increasing
27 levels of responsibility at Johnson & Johnson (J&J) for nearly 20 years,
28 including worldwide president of one of the company's divisions. Mr.
Zovighian serves as an advisory board member for the Leonard D. Schaeffer
Center for Health Policy & Economics at the University of Southern
California.

Defendant Wood

1 25. Defendant Wood has served as the Company's Corporate Vice President and
2 Group President of TAVR and Surgical Structural Heart Therapies since January 2023.
3 Previously, Defendant Wood served as the Company's Corporate Vice President, TAVR,
4 since 2007. According to the 2024 Proxy Statement, as of January 31, 2024, Defendant
5 Wood beneficially owned 372,945 shares of the Company's common stock. Given that the
6 price per share of the Company's common stock at the close of trading on January 31, 2024
7 was \$78.47, Defendant Wood owned approximately \$29.2 million worth of Edwards stock
8 as of that date.

9 26. The 2024 Proxy Statement stated the following about Defendant Wood:

10 Mr. Wood has been Corporate Vice President and Group President,
11 Transcatheter Aortic Valve Replacement (TAVR) and Surgical Structural
12 Heart, since January 2023. Mr. Wood previously served as Corporate Vice
13 President, TAVR, since 2007. Under his leadership, Edwards has experienced
14 extraordinary growth in the global TAVR business. Prior to assuming his
15 current role, he served as Vice President and General Manager, Percutaneous
16 Valve Interventions, from 2004 to 2007. Mr. Wood has more than 35 years of
17 experience in the medical technology industry at both Edwards and Baxter
18 Healthcare Corporation in positions including manufacturing management,
19 regulatory affairs and strategic and clinical marketing, primarily for the
20 surgical heart valve therapy business. Mr. Wood is a frequently invited faculty
21 member at key interventional cardiology and cardiothoracic surgery scientific
22 congresses. He previously held key positions in manufacturing management,
23 regulatory affairs, and strategic and clinical marketing, primarily in the
24 Company's leading surgical heart valve franchise. Mr. Wood is also a
25 passionate supporter of the United Way Orange County's Destination
26 Graduation Program which encourages at-risk high school students to
27 graduate and pursue higher education.

28 **Defendant Ullem**

29 27. Defendant Ullem has served as the Corporate Vice President and CFO of the
30 Company since 2014. According to the 2024 Proxy Statement, as of January 31, 2024,
31 Defendant Ullem beneficially owned 490,188 shares of the Company's common stock.
32 Given that the price per share of the Company's common stock at the close of trading on
33

1 January 31, 2024 was \$78.47, Defendant Ullem owned approximately \$38.5 million worth
2 of Edwards stock as of that date.

3 28. During the Relevant Period, while the Company's stock price was artificially
4 inflated and before the scheme was exposed, Defendant Ullem made the following sales of
5 Company common stock:

Date	Number of Shares	Avg. Price/ Share (\$)	Proceeds (\$)
February 29, 2024	7,255	\$85.59	\$620,926
April 1, 2024	7,255	\$95.16	\$690,371
April 30, 2024	7,250	\$86.07	\$624,007
May 21, 2024	5,625	\$90.45	\$508,803
June 20, 2024	5,625	\$87.79	\$493,818

14 Thus, in total, before the fraud was exposed, Defendant Ullem sold 33,010 shares of
15 Company stock on inside information, for which he received approximately \$2.9 million
16 in total proceeds. His insider sale, made with knowledge of material nonpublic information
17 before the material misstatements and omissions were exposed, demonstrate his motive in
18 facilitating and participating in the scheme.

19 29. The 2024 Proxy Statement stated the following about Defendant Ullem:

20 Mr. Ullem has been Corporate Vice President, Chief Financial Officer, since
21 January 2014. In addition, Mr. Ullem has executive responsibility for the
22 Company's information technology, information security, risk management,
23 indirect sourcing, and corporate services teams. Prior to joining Edwards, he
24 served as Chief Financial Officer of Bemis Company Inc., a Fortune 500
25 publicly traded global supplier of packaging and pressure sensitive materials
26 used in leading food, consumer, and healthcare products, from May 2010 to
27 December 2013. Mr. Ullem also had leadership responsibility for one of
28 Bemis' three business segments and the company's information technology
function. Prior to Bemis, Mr. Ullem spent 17 years in investment banking,
serving as Managing Director at Goldman Sachs and later at Bank of America.
Mr. Ullem currently serves on the board of directors of Illumina. He is also a

1 Henry Crown Fellow at the Aspen Institute.

2 **Defendant Davis**

3 30. Defendant Davis has served as a Company director since May 2024. She is
4 also a member of the Compensation and Governance Committee.

5 31. The 2024 Proxy Statement stated the following about Defendant Brenner:

6 Ms. Davis has more than 30 years of experience in health care, with a
7 particular emphasis on operations and developing businesses and services.
8 Her strong experience as a chief executive officer and leading operations
9 at large health services organizations will add a critical perspective and
10 provide unique insights during our strategic Board discussions, especially
11 as we navigate an evolving and complex healthcare environment for
12 healthcare practitioners and patients alike. Ms. Davis understands the
13 pressure points of health systems and can contribute with practical
14 knowledge to enhance our Board's ability to proactively prepare for, and
15 respond to, health industry challenges and opportunities.

16 **Defendant Gallahue**

17 32. Defendant Gallahue has served as a Company director since 2015. He also
18 serves as a member of the Audit Committee. According to the 2024 Proxy Statement, as of
19 January 31, 2024, Defendant Gallahue beneficially owned 70,277 shares of the Company's
20 common stock. Given that the price per share of the Company's common stock at the close
21 of trading on January 31, 2024 was \$78.47, Defendant Gallahue owned approximately \$5.5
22 million worth of Edwards stock as of that date.

23 33. During the Relevant Period, while the Company's stock price was artificially
24 inflated and before the scheme was exposed, Defendant Gallahue made the following sale
25 of Company common stock:

Date	Number of Shares	Avg. Price/ Share (\$)	Proceeds (\$)
February 23, 2024	3,058	\$87.61	\$267,911

26 Thus, in total, before the fraud was exposed, Defendant Gallahue sold 3,058 shares of
27 Company stock on inside information, for which he received approximately \$267,911 in
28

1 total proceeds. His insider sale, made with knowledge of material nonpublic information
2 before the material misstatements and omissions were exposed, demonstrate his motive in
3 facilitating and participating in the scheme.

4 34. The 2024 Proxy Statement stated the following about Defendant Gallahue:

5 Mr. Gallahue provides valuable insights and direction to our Board gained
6 through extensive executive management experience at medical
7 technology companies. His leadership roles on other public company
8 boards and committees and prior experience as a public company chief
9 financial officer also enable him to contribute informed financial and
10 accounting perspectives to our Board and Audit Committee. Throughout
11 his career, Mr. Gallahue has gained expertise and experience in areas that
12 we believe are important to the success of our Company as we execute on
13 our patient-focused innovation strategy, including experience in the
14 medical technology industry, as a senior executive managing global
15 operations, risk management and oversight, marketing and corporate
16 strategy.

17 **Defendant Heisz**

18 35. Defendant Heisz has served as a Company director since 2016. She also serves
19 as the Chair of the Audit Committee. According to the 2024 Proxy Statement, as of January
20 31, 2024, Defendant Heisz beneficially owned 44,075 shares of the Company's common
21 stock. Given that the price per share of the Company's common stock at the close of trading
22 on January 31, 2024 was \$78.47, Defendant Heisz owned approximately \$3.5 million
23 worth of Edwards stock as of that date.

24 36. During the Relevant Period, while the Company's stock price was artificially
25 inflated and before the scheme was exposed, Defendant Heisz made the following sale of
26 Company common stock:

Date	Number of Shares	Avg. Price/ Share (\$)	Proceeds (\$)
February 8, 2024	7,056	\$86.45	\$609,991

1 Thus, in total, before the fraud was exposed, Defendant Heisz sold 7,056 shares of
2 Company stock on inside information, for which she received approximately \$609,991 in
3 total proceeds. Her insider sale, made with knowledge of material nonpublic information
4 before the material misstatements and omissions were exposed, demonstrate her motive in
5 facilitating and participating in the scheme.

6 37. The 2024 Proxy Statement stated the following about Defendant Heisz:

7 Ms. Heisz's career in the banking industry, in-depth knowledge of capital
8 markets, and previous public company board and audit committee
9 experience enhances our Board's ability to effectively oversee financial
10 reporting, enterprise and operational risk management, as well as corporate
11 finance, tax, treasury, and governance matters. Serving as a director for
12 global companies and having led a global team, Ms. Heisz also brings with
13 her international experience as well as experience in areas including
14 finance and the financial industry, mergers and acquisitions in addition to
15 regulatory and compliance. Ms. Heisz's many years of experience as a
16 senior executive and board member has demonstrated invaluable
17 contributions as not only a member of the Board but also in her leadership
18 as Chairperson of the Audit Committee.

19 **Defendant LaViolette**

20 38. Defendant LaViolette has served as a Company director since 2020. He also
21 serves as the Chair of the Compensation and Governance Committee. According to the
22 2024 Proxy Statement, Defendant LaViolette beneficially owned 4,915 shares of the
23 Company's common stock. Given that the price per share of the Company's common stock
24 at the close of trading on January 31, 2024 was \$78.47, Defendant LaViolette owned
25 approximately \$385,680 worth of Edwards stock as of that date.

26 39. The 2024 Proxy Statement stated the following about Defendant LaViolette:

27 As a result of his over 40 years in the medical technology industry, Mr.
28 LaViolette brings extensive global executive experience. His many years
29 of working with large, global organizations and start-ups, which he
continues to do today, provides him with a unique perspective on strategy
and innovation as well as corporate development. Mr. LaViolette also has
experience in many other areas, including operations management, human
capital resources, marketing and communications, corporate strategy and

1 corporate governance. In addition, Mr. LaViolette's service on other
2 boards, including numerous chairmanships, has enabled him to be a
3 valuable contributor, offering astute insight in the strategic discussions at
4 our Board and Compensation and Governance Committee meetings.

5 **Defendant Loranger**

6 40. Defendant Loranger has served as a Company director since 2016. He also
7 serves as a member of the Audit Committee. According to the 2024 Proxy Statement,
8 Defendant Loranger beneficially owned 80,760 shares of the Company's common stock.
9 Given that the price per share of the Company's common stock at the close of trading on
10 January 31, 2024 was \$78.47, Defendant Loranger owned approximately \$6.3 million
11 worth of Edwards stock as of that date.

12 41. The 2024 Proxy Statement stated the following about Defendant Loranger:

13 Mr. Loranger is a seasoned executive with global manufacturing and
14 operational experience in highly regulated, high-tech industries. His
15 decades of experience leading large, global innovation-focused
16 corporations with intensive data privacy components is particularly
17 valuable to our Board. Through his many years of experience as an
18 international executive and as a member of other public company boards,
19 Mr. Loranger also brings expertise and experience in many other critical
20 areas for our Company, including operations management, financial
21 reporting, finance and the financial industry, innovations and technology
22 and corporate strategy. His expertise in risk management and oversight as
23 well as cybersecurity and information technology has allowed for engaged
24 contributions to the Board and the Audit Committee.

25 **Defendant Marsh**

26 42. Defendant Marsh served as a Company director from 2015 until the annual
27 meeting on May 7, 2024. During her time on the Board, Defendant Marsh served as the
28 Lead Independent Director and as a member of the Compensation and Governance
Committee. According to the 2024 Proxy Statement, Defendant Marsh beneficially owned
29,077 shares of the Company's common stock. Given that the price per share of the
Company's common stock at the close of trading on January 31, 2024 was \$78.47,

1 Defendant Marsh owned approximately \$2.3 million worth of Edwards stock as of that
2 date.

3 43. The Schedule 14A the Company filed with the SEC on March 28, 2023 (the
4 “2023 Proxy Statement”) stated the following about Defendant Marsh:

5 Ms. Marsh’s experience of more than 30 years in an increasingly complex
6 and evolving healthcare system as a president and chief executive officer,
7 combined with years of board experience that includes corporate
8 governance chairmanships, provide a unique perspective as our Board
9 considers the execution of our patient-focused innovation strategy. In her
10 role as the Lead Independent Director, Ms. Marsh has been invaluable in
11 partnering with the Chairman and representing the viewpoints and
12 perspectives of our independent directors. She has also been instrumental
13 as a member of the engagement team, communicating with shareholders
14 regarding the Company, including board structure, governance,
15 compensation and sustainability topics.

16 **Defendant Mussallem**

17 44. Defendant Mussallem served as the Chair of the Board from 2000 until the
18 annual meeting on May 7, 2024. He also previously served as the CEO of the Company
19 from 2000 until May 2023. According to the 2024 Proxy Statement, Defendant Mussallem
20 beneficially owned 5,144,627 shares of the Company’s common stock. Given that the price
21 per share of the Company’s common stock at the close of trading on January 31, 2024 was
22 \$78.47, Defendant Mussallem owned approximately \$403.7 million worth of Edwards
23 stock as of that date.

24 45. During the Relevant Period, while the Company’s stock price was artificially
25 inflated and before the scheme was exposed, Defendant Mussallem made the following
26 sales of Company common stock:

Date	Number of Shares	Avg. Price/ Share (\$)	Proceeds (\$)
March 4, 2024	29,350	\$86.63	\$2,542,590
April 4, 2024	29,350	\$93.04	\$2,730,665

1	May 2, 2024	29,350	\$84.81	\$2,489,026
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2 Thus, in total, before the fraud was exposed, Defendant Mussallem sold 88,050 shares of
3 Company stock on inside information, for which he received approximately \$7.8 million
4 in total proceeds. His insider sales, made with knowledge of material nonpublic
5 information before the material misstatements and omissions were exposed, demonstrate
6 his motive in facilitating and participating in the scheme.

7 46. The 2023 Proxy Statement stated the following about Defendant Mussallem:

8 Mr. Mussallem has extensive knowledge of, and deep expertise in, the
9 medical technology industry, and of the people, operations, processes and
10 products of the Company in particular. He has built an over 40-year career
11 with the Company and its predecessor from which he has developed
12 experiences and expertise in a wide range of areas, including innovation
13 and technology, risk management and oversight, operations management,
14 corporate strategy, and corporate governance. In addition, in his roles with
15 AdvaMed and other healthcare-related organizations, he has become a
16 recognized leader in the medical technology industry, making important
17 contributions to healthcare policy discussions in California, the United
18 States and the key global markets that the Company serves. These
19 experiences have established relationships, which are helpful in
20 developing our Board's strategic perspective, and enhanced his leadership
21 of the Company and contributions to our Board.

22 **Defendant Sequeira**

23 47. Defendant Sequeira has served as a Company director since 2020. She also
24 serves as a member of the Audit Committee. According to the 2024 Proxy Statement,
25 Defendant Sequeira beneficially owned 8,218 shares of the Company's common stock.
26 Given that the price per share of the Company's common stock at the close of trading on
27 January 31, 2024 was \$78.47, Defendant Sequeira owned approximately \$644,866 worth
28 of Edwards stock as of that date.

48. The 2024 Proxy Statement stated the following about Defendant Sequeira:

50 Ms. Sequeira has over 25 years of experience in the pharmaceutical
51 industry through her work with Takeda and, prior to that, with Eli Lilly.
52 She currently leads Takeda's Global Portfolio Division, and, in this role,

1 she oversees roughly 11,000 employees across Takeda's global Vaccines
2 business including manufacturing, research and development and
3 commercial; the Global Commercial and Medical organizations, and all of
4 Takeda's markets across Europe and Canada, Growth and Emerging
5 Markets, and China. Her experience in leadership roles in multiple
6 markets, across cultures and within different healthcare systems where she
7 has successfully launched products, transformed businesses, and delivered
8 sustainable growth is particularly valuable for our global business. In
9 addition, throughout her career, she has developed experience in other
10 areas, including finance and mergers and acquisitions, innovation and
11 technology, risk management and oversight, artificial intelligence and
12 data, corporate responsibility, sustainability and human capital resources,
13 all of which allow her to provide valuable contributions to our Board and
14 the Audit Committee. Ms. Sequeira's industry experience with
15 pharmaceutical innovation and patient access provides important expertise
16 to our Board as Edwards executes on its patient-focused innovation
17 strategy.

18 **Defendant Valeriani**

19 49. Defendant Valeriani has served as a Company director since 2014, and has
20 served as the Board Chair since May 2024. He also serves as a member of the
21 Compensation and Governance Committee. According to the 2024 Proxy Statement,
22 Defendant Valeriani beneficially owned 66,111 shares of the Company's common stock.
23 Given that the price per share of the Company's common stock at the close of trading on
24 January 31, 2024 was \$78.47, Defendant Valeriani owned approximately \$5.2 million
25 worth of Edwards stock as of that date.

26 50. The 2024 Proxy Statement stated the following about Defendant Valeriani:
27 With 40 years of medical technology industry experience in a large and
28 complex global company and experience directing corporate strategy, Mr.
29 Valeriani provides critical perspectives to our Board's oversight of the
30 development of our patient-focused innovation strategy and assessment of
31 future business investments and opportunities. His deep operational
32 experience provides invaluable insights to our Board. In addition, through his
33 professional career as well as his service on other public company boards, Mr.
34 Valeriani has extensive experience in human capital resources at a global
35 company which enables him to contribute valuable perspectives and provide

1 strong leadership and direction as the Chairperson of our Board's
2 Compensation and Governance Committee.

3 **FIDUCIARY DUTIES OF THE INDIVIDUAL DEFENDANTS**

4 51. By reason of their positions as officers, directors, and/or fiduciaries of
5 Edwards and because of their ability to control the business and corporate affairs of
6 Edwards, the Individual Defendants owed Edwards and its shareholders fiduciary
7 obligations of trust, loyalty, good faith, and due care, and were and are required to use their
8 utmost ability to control and manage Edwards in a fair, just, honest, and equitable manner.
9 The Individual Defendants were and are required to act in furtherance of the best interests
10 of Edwards and its shareholders so as to benefit all shareholders equally.

11 52. Each director and officer of the Company owes to Edwards and its
12 shareholders the fiduciary duty to exercise good faith and diligence in the administration
13 of the Company and in the use and preservation of its property and assets and the highest
14 obligations of fair dealing.

15 53. The Individual Defendants, because of their positions of control and authority
16 as directors and/or officers of Edwards, were able to and did, directly and/or indirectly,
17 exercise control over the wrongful acts complained of herein.

18 54. To discharge their duties, the officers and directors of Edwards were required
19 to exercise reasonable and prudent supervision over the management, policies, controls,
20 and operations of the Company.

21 55. Each Individual Defendant, by virtue of their position as a director and/or
22 officer, owed to the Company and to its shareholders the highest fiduciary duties of loyalty,
23 good faith, and the exercise of due care and diligence in the management and
24 administration of the affairs of the Company, as well as in the use and preservation of its
25 property and assets. The conduct of the Individual Defendants complained of herein
26 involves a knowing and culpable violation of their obligations as directors and officers of
27 Edwards, the absence of good faith on their part, or a reckless disregard for their duties to
28 the Company and its shareholders that the Individual Defendants were aware or should

1 have been aware posed a risk of serious injury to the Company. The conduct of the
2 Individual Defendants who were also officers and directors of the Company has been
3 ratified by the remaining Individual Defendants who collectively comprised the
4 Company's Board at all relevant times.

5 56. As senior executive officers and/or directors of a publicly-traded company
6 whose common stock was registered with the SEC pursuant to the Exchange Act and traded
7 on the NYSE, the Individual Defendants had a duty to prevent and not to effect the
8 dissemination of inaccurate and untruthful information with respect to the Company's
9 financial condition, performance, growth, operations, financial statements, business,
10 products, management, earnings, internal controls, and present and future business
11 prospects, including the dissemination of false information regarding the Company's
12 business, prospects, and operations, and had a duty to cause the Company to disclose in its
13 regulatory filings with the SEC all those facts described in this complaint that it failed to
14 disclose, so that the market price of the Company's common stock would be based upon
15 truthful and accurate information. Further, they had a duty to ensure the Company remained
16 in compliance with all applicable laws.

17 57. To discharge their duties, the officers and directors of the Company were
18 required to exercise reasonable and prudent supervision over the management, policies,
19 practices, and internal controls of the Company. By virtue of such duties, the officers and
20 directors of Edwards were required to, among other things:

21 (a) ensure that the Company was operated in a diligent, honest, and prudent
22 manner in accordance with the laws and regulations of Delaware, California, and the
23 United States, and pursuant to Edwards's corporate governance and applicable business
24 practice standards;

25 (b) conduct the affairs of the Company in an efficient, business-like manner
26 so as to make it possible to provide the highest quality performance of its business, to avoid
27 wasting the Company's assets, and to maximize the value of the Company's stock;

(c) remain informed as to how Edwards conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, to make reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices;

(d) establish and maintain systematic and accurate records and reports of the business and internal affairs of Edwards and procedures for the reporting of the business and internal affairs to the Board and to periodically investigate, or cause independent investigation to be made of, said reports and records;

(e) maintain and implement an adequate and functioning system of internal legal, financial, and management controls, such that Edwards's operations would comply with all applicable laws and Edwards's financial statements and regulatory filings filed with the SEC and disseminated to the public and the Company's shareholders would be accurate;

(f) exercise reasonable control and supervision over the public statements made by the Company's officers and employees and any other reports or information that the Company was required by law to disseminate;

(g) refrain from unduly benefiting themselves and other Company insiders at the expense of the Company; and

(h) examine and evaluate any reports of examinations, audits, or other financial information concerning the financial affairs of the Company and to make full and accurate disclosure of all material facts concerning, *inter alia*, each of the subjects and duties set forth above.

58. Each of the Individual Defendants further owed to Edwards and its shareholders the duty of loyalty requiring that each favor Edwards's interest and that of its shareholders over their own while conducting the affairs of the Company and refrain from using their position, influence or knowledge of the affairs of the Company to gain personal advantage.

1 59. At all times relevant hereto, the Individual Defendants were the agents of each
2 other and of Edwards and were at all times acting within the course and scope of such
3 agency.

4 60. Because of their advisory, executive, managerial, directorial, and controlling
5 positions with Edwards, each of the Individual Defendants had access to adverse,
6 nonpublic information about the Company.

7 61. The Individual Defendants, because of their positions of control and authority,
8 were able to and did, directly or indirectly, exercise control over the wrongful acts
9 complained of herein, as well as the contents of the various public statements issued by
10 Edwards.

11 **CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION**

12 62. In committing the wrongful acts alleged herein, the Individual Defendants
13 have pursued, or joined in the pursuit of, a common course of conduct, and have acted in
14 concert with and conspired with one another in furtherance of their wrongdoing. The
15 Individual Defendants caused the Company to conceal the true facts as alleged herein. The
16 Individual Defendants further aided and abetted and/or assisted each other in breaching
17 their respective duties.

18 63. The purpose and effect of the conspiracy, common enterprise, and/or common
19 course of conduct was, among other things, to: (i) facilitate and disguise the Individual
20 Defendants' violations of law, including breaches of fiduciary duty, unjust enrichment,
21 waste of corporate assets, gross mismanagement, abuse of control, and violations of the
22 Exchange Act; (ii) conceal adverse information concerning the Company's operations,
23 financial condition, legal compliance, future business prospects, and internal controls; and
24 (iii) artificially inflate the Company's stock price.

25 64. The Individual Defendants accomplished their conspiracy, common
26 enterprise, and/or common course of conduct by causing the Company purposefully or
27 recklessly to conceal material facts, fail to correct such misrepresentations, and violate
28

1 applicable laws. In furtherance of this plan, conspiracy, and course of conduct, the
2 Individual Defendants collectively and individually took the actions set forth herein.
3 Because the actions described herein occurred under the authority of the Board, each of the
4 Individual Defendants who is a director of Edwards was a direct, necessary, and substantial
5 participant in the conspiracy, common enterprise, and/or common course of conduct
6 complained of herein.

7 65. Each of the Individual Defendants aided and abetted and rendered substantial
8 assistance in the wrongs complained of herein. In taking such actions to substantially assist
9 the commission of the wrongdoing complained of herein, each of the Individual Defendants
10 acted with actual or constructive knowledge of the primary wrongdoing, either took direct
11 part in, or substantially assisted in the accomplishment of that wrongdoing, and was or
12 should have been aware of his or her overall contribution to and furtherance of the
13 wrongdoing.

14 66. At all relevant times hereto, each of the Individual Defendants was the agent
15 of each of the other Individual Defendants and of Edwards and was at all times acting
16 within the course and scope of such agency.

17 **EDWARDS'S BUSINESS STANDARDS AND CORPORATE GOVERNANCE**

18 ***Edwards's Business Standards***

19 67. Edwards's Global Business Practice Standards (the "Business Standards")
20 states that Edwards "take[s] pride in conducting our business with honesty, openness and
21 fairness and in accordance with legal standards and the highest ethical principles because
22 it is the right thing to do."

23 68. Further, the Business Standards state that they apply to "all of Edwards'
24 businesses and subsidiaries and to all employees, members of the Board of Directors and
25 agents of Edwards."

26 69. In a section titled "Waivers and Amendments," the Business Standards state
27 the following, in pertinent part, "We will waive application of the policies set forth in our
28

1 Standards only where circumstances warrant granting a waiver. Waivers for directors and
2 executive officers may be made only by the Board of Directors or its designated committee
3 and must be promptly disclosed as required by law or regulation.”

4 70. In a section titled “Fraud,” the Business Standards state the following, in
5 pertinent part:

6 Preventing and detecting fraud is key to keeping our reputation sound and
7 avoiding costly issues and missed opportunities. Fraud generally involves
8 some form of deception—such as theft or making a false statement—in order to
9 obtain a financial benefit or other advantage. We insist on integrity in all of
10 our work and the work of our partners. Fraud is prohibited, even if it is meant
11 to benefit Edwards.

12 Be aware of these potential fraud red flags:

13 * * *

14 • Misrepresentations about products or services to gain or protect business
15 • Failure to disclose required information

16 71. In a section titled “Communications with Investors,” the Business Standards
17 state the following, in pertinent part:

18 All public disclosures, including reports and documents filed with the U.S.
19 Securities and Exchange Commission, press releases, speeches and other
20 communications must be honest, accurate, timely and representative of the
21 facts. As part of our commitment, we:

22 • Do not make disclosures on a selective basis, but we do disclose material
23 information to the public in compliance with U.S. securities laws
24 • Ensure that our disclosures are full, fair, timely and understandable
25 • Comply with Company accounting policies and procedures as required and
26 cooperate fully with internal and external auditors

27 72. In a section titled “Conflicts of Interest,” the Business Standards state the
28 following, in pertinent part:

A conflict of interest can arise when we put our personal interests ahead of

1 Edwards' interests.

2 Even the appearance of a conflict of interest can be damaging to our Company
3 or ourselves. You must do all you can to identify potential conflicts, avoid
4 situations where they might arise and disclose any potential or actual conflict
5 of interest promptly to your manager, Human Resources or the Compliance
6 department.

7 Conflicts can arise in situations where you use your role at Edwards to pursue
8 business opportunities or other benefits for yourself or for those closest to you,
9 such as your family members and friends. You are expected to make decisions
10 and take actions based on the best interests of our Company, not for yourself
11 or persons close to you.

12 73. In a section titled "Inside Information," the Business Standards state the
13 following, in relevant part:

14 It is illegal to buy or sell stock or other securities when aware of inside
15 information about a company that is material and has not been disclosed to
16 the public. It is also illegal to give this information to others so that they can
17 trade. Material information is any news or fact that a reasonable investor could
18 consider important in deciding whether to buy, sell or hold the securities of a
19 company. The materiality of the information must be viewed in light of the
20 certainty and the impact the information could have on Edwards as a whole.

21 * * *

22 Trading on this information may create an unfair advantage, so if you are in
23 possession of any Edwards material, non-public information, you may not
24 buy or sell Edwards securities or otherwise use the information for personal
25 gain.

26 Upon receipt of any such information, the Disclosure Committee shall
27 investigate the matter, consult with senior management as warranted, confer
28 with the Audit Committee of Edwards Group's Board of Directors if
appropriate, and ensure that any necessary corrective action is taken.

29 74. In violation of the Business Standards, the Individual Defendants conducted
30 little, if any, oversight of the Individual Defendants' scheme to issue materially false and
31 misleading statements to the public and to facilitate and disguise the Individual
32 Defendants' violations of law, including but not limited to, breaches of fiduciary duty,

1 abuse of control, gross mismanagement, waste of corporate assets, violations of the
2 Exchange Act, and unjust enrichment, including five Defendants who sold Company stock
3 on inside information. Also, in violation of the Business Standards, the Individual
4 Defendants failed to maintain the accuracy of Edwards's records and reports, failed to
5 maintain internal controls, and failed to comply with laws and regulations, conduct
6 business in an honest and ethical manner, and properly report violations of the Business
7 Standards.

8 ***Edwards's Audit Committee Charter***

9 75. Edwards's Audit Committee Charter ("Audit Committee Charter") states that
10 the purpose of the Audit Committee is as follows:

- 11 • integrity of the Corporation's financial statements;
- 12 • independent auditor's qualifications and independence;
- 13 • performance of the Corporation's internal audit function and
14 independent auditors;
- 15 • Corporation's compliance with legal and regulatory requirements;
- 16 • Corporation's disputes and litigation;
- 17 • Corporation's investment and hedging activities; and
- 18 • Corporation's enterprise-wide risk management practices.

19 76. Regarding the Audit Committee's "Key Responsibilities," the Audit
20 Committee Charter states the following:

21 The Committee's job is one of oversight and it recognizes that the
22 Corporation's management is responsible for preparing the Corporation's
23 financial statements and determining that such financial statements are
24 complete and accurate and are in accordance with generally accepted
25 accounting principles, and that the outside auditors are responsible for
26 planning and conducting the audits of those financial statements.
27 Additionally, the Committee recognizes that financial management, including
28 the internal audit staff as well as the outside auditors, have more time,
knowledge, expertise and detailed information on the Corporation than do
Committee members; consequently, in carrying out its oversight
responsibilities, the Committee is not providing any expert or special
assurance as to the Corporation's financial statements or any professional
certification as to the outside or internal auditor's work.

77. Regarding the Audit Committee's responsibilities for "External Auditor Engagement and Activities," the Audit Committee states, in relevant part:

- Appoint, retain, terminate, determine compensation for and oversee the independent auditor to audit the Corporation's consolidated financial statements and perform other audit, review and attest services. The independent auditor shall report directly to the Committee, and the Committee will be authorized to resolve disputes between management and the independent auditor regarding the audit.
- Review and pre-approve all audit and non-audit services to be provided to the Corporation by the independent auditor in accordance with applicable laws, rules and regulations, subject to any exceptions for pre-approval for de minimis non-audit services provided in applicable laws, rules and regulations. The Committee may delegate authority to grant such pre-approvals to one or more members of the Committee, provided the full Committee is informed of the grant of any such preapproval at its next scheduled meeting.
- Meet with the independent auditor and management to review the proposed audit scope and procedures to be utilized. Regularly review with the independent auditor any audit problems or difficulties and management's response including any restrictions on the scope of the independent auditor's activities or on access to requested information, and any significant disagreements with management. The review should also include discussion of the responsibilities, budget and staffing of the internal audit function.

* * *

- Obtain and review prior to the completion of the independent auditor's audit of the Corporation's year-end financial statements, a report from the independent auditor, describing (a) all critical accounting policies and practices to be used in such audit, (b) all alternative treatments of financial information within generally accepted accounting principles that have been discussed with management, ramifications of the use of such alternative disclosures and treatments, and the treatment preferred by the independent auditor, (c) other material written communications between the independent auditor and management, such as any management letter or schedule of unadjusted differences, and (d) any other matters required to be communicated by the independent auditors to the Committee with respect to the review or audit of the Corporation's financial statements pursuant to applicable auditing standards adopted by the Public Company Accounting Oversight Board (the "PCAOB"). The Committee should review any reports

1 on such topics or similar topics prepared by management and discuss with the
2 independent auditor and management any material issues raised in such
3 reports.

4 78. Regarding the Audit Committee's responsibilities for "Internal Audit," the
5 Audit Committee states:

- 6 • Review the qualifications and organizational structure of the internal
7 audit function and concur in the appointment, replacement, reassignment or
8 dismissal of the individual responsible for the Corporation's internal audit
9 function, who shall report directly to the Committee.
- 10 • Review the proposed audit plan of the internal auditor, including the
11 independence and authority of the internal auditor's reporting obligations, the
12 adequacy of internal audit resources and the coordination and completeness
13 of coverage between the internal and independent auditors.
- 14 • Receive periodic summaries of findings from completed internal audits
15 and, as appropriate, the status of major audits in process. Receive progress
16 reports on the completion of the current year's internal audit plan, including
17 explanations for any significant deviations from the plan.

18 79. Regarding the Audit Committee's responsibilities for "Risk Management,"
19 the Audit Committee states:

- 20 • Discuss guidelines and policies with respect to risk assessment and risk
21 management, including treasury risks, legal and compliance risks and risks
22 related to information technology, information security, cybersecurity, and the
23 Corporation's enterprise risk management practices, it being understood that
24 it is the job of management to assess and manage the Corporation's exposure
25 to risk.
- 26 • Receive periodic reports on the Corporation's overall risk management
27 process and review significant risks and exposures identified by management,
28 the internal auditors and the independent auditors, including the steps
management has taken to monitor and control such risks and exposures.

29 80. Regarding the Audit Committee's responsibilities for "Financial Reporting,"
30 the Audit Committee states:

- 31 • Meet to review and discuss with management and the independent
32 auditor the consolidated financial statements that will be contained in the
33 Corporation's annual and quarterly reports, including reviewing the
34 Corporation's specific disclosures under "Management Discussion and

1 Analysis of Financial Condition and Results of Operations.”

2

3 • Discuss earnings press releases, as well as financial information and
4 earnings guidance provided to analysts and ratings agencies, paying particular
5 attention to any use of “proforma,” or “adjusted” non-GAAP information, it
6 being understood that such discussions may, in the discretion of the
7 Committee, be done generally (i.e., by discussing the types of information to
8 be disclosed and the type of presentation to be made) and that the Committee
9 need not discuss in advance each earnings release or each instance in which
10 the Corporation gives earnings guidance.

11

12 • Discuss with the independent auditor the auditor’s judgments about the
13 quality and the acceptability of accounting principles used to prepare the
14 Corporation’s consolidated financial statements. Review with management
15 and the independent auditor the impact on the annual financial statements of
16 any significant accounting and financial reporting issues and judgments made
17 in connection with the preparation of the financial statements, any matters
18 arising from the audit of the Corporation’s financial statements that are
19 expected to constitute “critical audit matters” as defined by applicable
20 PCAOB auditing standards, as well as recent professional and regulatory
21 pronouncements and any newly adopted or proposed changes in accounting
22 principles that would significantly affect the Corporation or its consolidated
23 financial statements.

24

25 • Review the Corporation’s financial reporting processes, based on
26 consultation with management, the independent auditor and internal auditor.
27 Such review shall include consideration of major issues regarding accounting
28 principles and financial statement presentations, including any significant
changes in the Corporation’s selection or application of accounting principles,
and major issues as to the adequacy of the Corporation’s internal controls and
any special audit steps adopted in light of identified deficiencies.

• Review the adequacy and effectiveness of the Corporation’s financial,
accounting and disclosure controls with management, the independent auditor
and the internal auditor, as appropriate, receiving recommendations for the
improvement of such controls and reviewing whether any such previously
approved recommendations have been implemented.

• Review annually the effect of off-balance sheet structures, if any, on
the Corporation’s financial statements.

81. Regarding the Audit Committee’s responsibilities for “Ethical and Legal

1 Compliance,” the Audit Committee states:

2 • Assist the Board in establishing and monitoring compliance with the
3 ethical business practice standards of the Corporation, and concur in the
4 appointment, replacement or dismissal of the Chief Compliance Officer (or
5 such other management position having responsibility for the Corporation’s
6 compliance function as the Committee shall designate by resolution), who will
7 report directly to the Committee. The Committee will also review the policies
8 of the Corporation to assure that they are consistent with its ethics and
9 business practices.

10 • Review the effectiveness of the system for monitoring compliance with
11 laws and regulations, including compliance relating to the Corporation’s
12 interactions with health care professionals, and receive reports from the
13 General Counsel or Chief Compliance Officer on the results of management’s
14 review of compliance with the Corporation’s policies and any investigations
15 by management related to significant fraudulent acts or irregularities.

16 • Evaluate whether management is setting the appropriate “tone at the
17 top” by communicating the importance of the Corporation’s ethical and
18 business practices standards, including compliance with the Corporation’s
19 Global Business Practice Standards.

20 • Periodically review with the General Counsel or Chief Compliance
21 Officer the Corporation’s preventive law program and activities, as well as
22 any legal and regulatory matters that may have a material impact on the
23 Corporation.

24 • Review with the General Counsel any legal matters that could have a
25 significant impact on the Corporation’s financial statements.

26 • Review and approve or ratify all related person transactions (which
27 term refers to transactions that are required to be disclosed pursuant to Item
28 404(a) of Regulation S-K adopted by the Securities and Exchange
Commission).

82. In violation of the Audit Committee Charter, the Individual Defendants conducted little, if any, oversight of the Company’s engagement in the Individual Defendants’ scheme to issue materially false and misleading statements to the public and to facilitate and disguise the Individual Defendants’ violations of law, including breaches

1 of fiduciary duty, unjust enrichment, gross mismanagement, abuse of control, waste of
2 corporate assets, and violations of the Exchange Act. Moreover, in violation of the Audit
3 Committee Charter, the Individual Defendants failed to maintain the accuracy of the
4 Company records and reports, comply with laws and regulations, act in good faith and
5 diligence without misstating, misrepresenting, or omitting material facts, and properly
6 report violations of the Audit Committee Charter.

7 **INDIVIDUAL DEFENDANTS' MISCONDUCT**

8 **Background**

9 83. Edwards is a medical sciences company that researches, produces, and
10 distributes treatments for heart valve repair and replacement therapies.. For over sixty
11 years, the Company has become a pioneer in the development of heart valve therapies.

12 84. The Company has four categories of therapies its specializes in: TMTT,
13 Surgical Structural Heart therapies, Critical Care therapies, and the Company's core
14 product, TAVR.

15 **False and Misleading Statements**

16 ***February 6, 2024 Press Release***

17 85. On February 6, 2024, Edwards published the FY 2023 Earnings Release,
18 disclosing its financial and operational results for the fourth quarter and year-end of the
19 2023 Fiscal Year.

20 86. The FY 2023 Earnings Release revealed that "Q4 TAVR sales grew 13
21 percent; constant currency sales grew 12 percent." The FY 2023 Earning Release also
22 quotes Defendant Zovighian, who highlighted that:

23 In 2023, our team made significant progress advancing transformational
24 therapies for patients while delivering strong financial performance. Full year
25 sales increased 12 percent, including impressive growth across each of our
26 four product groups. We exited the year with strong momentum driven by our
27 broad portfolio of innovative therapies. In 2024, we anticipate launching
28 multiple breakthrough technologies globally and advancing important clinical
trials as we embark on a new era of structural heart innovation. These
breakthroughs, along with significant unmet patient needs, give us confidence

1 in our ability to accelerate growth in 2025 and beyond.

2 87. In discussing the TAVR results for the quarter, the FY 2023 Earnings Release
3 stated:

4 For the quarter, the company reported global TAVR sales of \$979 million, an
5 increase of 13 percent versus the prior year, or 12 percent on a constant
6 currency basis. Performance was driven by double-digit constant currency
7 growth in the U.S., Europe and Japan. ***The company's competitive position
was stable globally and local selling prices were also stable.***²

8 In the U.S., the company remains pleased with the continued expansion and
9 adoption of the SAPIEN 3 Ultra RESILIA platform. This technology builds
10 on Edwards' leadership in tissue technology and durability by combining
11 advancements in tissue science with the industry leading SAPIEN 3 Ultra
12 valve to offer the only dry storage transcatheter heart valve for U.S. patients
13 today. ***The company remains confident that the future of TAVR remains
strong driven by an increased focus on patient activation, a platform that
delivers lifetime management for aortic stenosis patients, advances in new
technologies such as RESILIA tissue, as well as indication expansion and
increased global adoption.***

15 Looking ahead, the company is pleased with the recently announced CE Mark
16 approval for the SAPIEN 3 Ultra RESILIA platform and plans a disciplined
17 launch in Europe. Long-term, the company continues to anticipate excellent
18 opportunities for growth, as international adoption of TAVR therapy remains
quite low.

19 ***February 6, 2024 Earnings Call***

20 88. That same day, the Company hosted an earnings call with investors and
21 analysts to discuss the fourth quarter and year-end financial results for the 2023 Fiscal Year
22 (the "FY 2023 Earnings Call").

23 89. During his scripted remarks on the FY 2023 Earnings Call, Defendant
24 Zovighian highlighted the TAVR performance for the Company, stating:

25 We are pleased with our strong 2023 financial performance with full year sales
26 up 12% to 6 billion, including strong growth across each of our four product
27 groups. We invested more than 1 billion in research and development, and we
achieved key strategic milestones, including the introduction of new

28 ² All emphasis added unless stated otherwise.

1 technologies and indication expansion to ensure sustainable healthy growth in
2 the near, mid and long term.

3 We exited the year with strong momentum with Q4 growth of 13% and TAVR
4 growth of 12%. These results were better than expected, driven by our broad
5 portfolio of innovative therapies.

6 90. Defendant Zovighian then went on to discuss the Company's TAVR
7 expectations for the upcoming 2024 Fiscal Year, stating:

8 In 2024, we are well--positioned to enter a new era of structural heart
9 innovation. In TAVR, we are strengthening our leadership. We are
10 experiencing strong adoption of our flagship SAPIEN 3 Ultra RESILIA and
11 continuing enrollment in our ALLIANCE pivotal trial for our next-gen TAVR
12 technology, SAPIEN X4.

13 91. Turning to the product by product breakdown, Defendant Zovighian stated of
14 the TAVR:

15 Now I will provide some additional detail by product group. ***In TAVR, our***
16 ***full year 2023 global sales of \$3.9 billion increased 10.6%, year-over-year.***
17 ***Our U.S. and OUS sales growth rates were similar. In the fourth quarter,***
18 ***our global TAVR sales of 979 million increased 12%, year-over-year.***
19 ***Performance was driven by double-digit growth in the U.S., Europe and***
20 ***Japan.***

21 The company competitive position was stable, globally, and local selling price
22 were also stable. In the U.S., we remain pleased with the continued expansion
23 and adoption of a SAPIEN free Ultra RESILIA platform. This technology
24 builds on Edward's long-standing leadership in tissue technology and
25 durability by combining advancements in tissue science with the
26 industryleading SAPIEN 3 Ultra valve.

27 22 Developing safe, effective and durable heart valve requires significant long-
28 term commitment, and we are proud to build on 65 years on valve innovation,
29 while leveraging the expertise and know-how of more than 2,000 engineers
30 and R&D specialists, across the company.

31 25 We are proud of uninterrupted leadership in structural heart and will continue
32 to invest vigorously in these platforms. ***In addition, our scaling of patient***
33 ***activation initiatives, along with next-gen TAVR and additional evidence on***
34 ***asymptomatic and moderate AS patients position us for healthy, sustainable***
35 ***TAVR growth well into the future.***

1 92. Discussing the TAVR's impact and growth internationally, Defendant
2 Zovighian stated:

3 ***Outside of the U.S., in the fourth quarter, our double-digit growth was
4 comparable with our global TAVR growth, driven by Europe and Japan.
5 Long term, we continue to anticipate excellent opportunities for growth.***

6 As the international adoption of TAVR therapy remained quite low in many
7 regions. In Europe, Edwards sales growth was driven by the broad-based
8 adoption of our SAPIEN platform. ***It is encouraging that the growth in Q4
9 was widespread across all major countries.*** Looking ahead, we are pleased
10 with the recently announced CE Mark approval for SAPIEN 3 Ultra
11 RESILIA, and we are planning for a disciplined launch.

12 We were pleased with our sales growth in Japan and as expected, we grew
13 faster than overall procedural growth. After more than 20 years of rigorous
14 clinical experience and over 1 million patients treated with SAPIEN around
15 the world, ***our TAVR platform is positioned for continued global leadership
16 and strong sustainable growth.***

17 ***Given the undertreatment rates, we are confident in the future of TAVR,
18 driven by greater awareness, patient activation, a platform that delivers
19 lifetime management for AS patients, advances in new technologies such as
20 RESILIA, as well as indication expansion and increased global adoption.***

21 93. Defendant Zovighian concluded his scripted remarks by stating that:
22 In TAVR, we will continue to drive global adoption of SAPIEN 3 Ultra
23 RESILIA, present pivotal trial data from early TAVR studying asymptomatic
24 AS patients and enrolling--and a pivotal trial studying the next-generation
25 SAPIEN X4.

26 94. Later on the FY 2023 Earnings Call, during the question-and-answer portion,
27 analysts asked multiple questions about the TAVR. For example, one JPMorgan analyst
28 asked about the TAVR market moving forward, with Defendants Wood and Zovighian
responding:

29 ***Robert Justin Marcus – JPMorgan Chase & Co.: Maybe one on the TAVR
30 market. We have the exciting data from early TAVR coming later this year at
31 TCT. How do you think about what that does to the TAVR market growth,
32 going forward? Do you put up double-digit growth in the fourth quarter.? That's what
33 guidance includes the next few years for the most part. How do***

1 you think about what's coming from low, intermediate and high risk and
2 severe? And then how do you think about what asymptomatic adds? Is that
3 just what helps keep you with double digit, or can that help accelerate growth?
4 Thanks.

5 *Defendant Wood:* Yeah, thanks, this is Larry. That's a great question. I think
6 the first thing is we're just going to learn a lot from this trial. There's a lot of
7 unknown questions out there in terms of what percentage of patients are truly
8 asymptomatic when subjected to a stress test. I think how fast do people
9 progress and what happens to people while they're waiting.

10 I think the biggest thing about it is, as we've talked about, and I spent a lot of
11 time at the investor conference, the time from a patient to get diagnosed to
12 treated is just really long. And a lot of that is the interpretation of the
13 guidelines and this overlay of symptoms. And it's all really sand in the gears
14 preventing the patients from moving through.

15 And unfortunately, given the deadliness of the disease, a lot of people never
16 actually make it to therapy. I think with the early TAVR trial, assuming that
17 it's successful, it will just streamline that process where we can just apply
18 guideline criteria to aortic stenosis, and it won't require this additional
19 evaluation of symptoms and people can just move through.

20 ***But remember, only about 13% of patients right now with severe aortic
21 stenosis actually get treated. So there's a huge under treatment right now.
22 We think asymptomatic just adds to that.***

23 *Defendant Zovighian:* In addition, Robbie, what I like is our commitment to-
24 -after 20 years of TAVR, we are still super committed to bring big evidence.
25 Look at these two trials, PROGRESS and EARLY TAVR. This is a potential
26 for sure to learn more, but also to expand indication, to change in the
27 guidelines. So as a leader in the space, for sure, we like it, we are committed.
28 ***But I believe that in the next 10 years, even TAVR, we are going to see some
very exciting things happening.***

29 95. Similarly, a Morgan Stanley analyst asked a question about the TAVR's
30 market share in Japan, to which Defendant Wood responded:

31 *Patrick Andrew Robert Wood – Morgan Stanley:* Amazing. Thanks for taking
32 the questions. I guess maybe for the first one on TAVR and Japan in general.
33 Do you think you've been taking back some share, post trialing. It sounded
34 like you feel very good about the market, and you were taking back some

1 share on that side. Just any color you could give there would be great.
2

3 *Defendant Wood:* Sure. I think what happens when new technology comes
4 into Japan just because of the way the certification process works and people
5 having to move through that process, that certainly had an impact for us. ***I***
think in Q4, we grew faster than the market. And I think that really relates
6 to some of the trialing ending and people kind of moving back to our platform.
7

8 But this is sort of something that goes on, ***but we're very pleased with how***
we grew in Japan in Q4 and continue to look forward to that market growing
because it's a very--it's a much lower penetrated market than places like the
U.S. and Europe. So we continue to see that as a long-term growth driver
for us.
9

10 96. A separate question, asked by an Evercore analyst, discussed using the TAVR
11 as a comparison to other products made by the Company. In response, Defendant
12 Zovighian stated:

13 *Vijay Muniyappa Kumar – Evercore ISI Institutional Equities:* Maybe on the
14 last question on EVOQUE, Daveen, you made some comments here about the
15 totality of data. But I'm curious on when you think about the market
16 development, is there like a bar, like do we need to see a stat significance in
17 mortality? Like, there's a reason this valve was called forgotten valve. So, I'm
18 curious what wakes up physicians to take the valve seriously, maybe compare
19 in contrast on how this adoption curve could look like versus, I don't know if
TAVR is a good example, but I would love your comments.
20

21 * * *

22 *Defendant Zovighian:* And we are very excited. Think about TAVR. Twenty
23 years later, we are still generating evidence. We are still innovating with Ultra
24 RESILIA X4. We still believe that there is a way for TAVR to grow healthy
25 double digit in the many years to come, globally. So here, for TMTT
26 EVOQUE, it's probably thinking the same. It is not the next five years, it's like
27 10 or 20 years here that we are thinking of.
28

29 97. Lastly, in response to a question from a Barclays analyst regarding field
30 activations and patient activation efforts, Defendants Ullem, Wood, and Zovighian
31 responded:
32

33 *Matthew Stephan Miksic – Barclays Bank PLC:* And then the TAVR side, did
34 you see any results, you feel ,from these field activations and patient activation
35 efforts in Q4? Or is that something that's still to come? Thanks.
36

1
2 *Defendant Ullem:* Yeah, Matt, I think we saw some benefit from the patient
3 activation initiatives that we have in place. It's tough to isolate those from the
4 other efforts that we have underway to continue to support the growth of
5 TAVR. ***But no, that's certainly helping drive growth in the fourth quarter,***
6 ***and beyond.***

7
8
9 *Defendant Wood:* ***Just to add on to this, I mean, I think it'd be being correct***
10 ***to say our patient activation efforts are just starting to pay dividends now.***
11 We've been doing patient activation for the last, I don't know, five or six years
12 through our digital campaigns through some of our website stuff, some of our
13 patient resources, some of the general cardiology awareness events we do and
14 a number of other things that have been driving this.

15 *So I think patient activation has been contributing all the way along the*
16 *way. I think what we're talking about now, though, is a much more*
17 *sophisticated approach and program to really tapping into these untreated*
18 *patients that are in the system, but hospitals don't really realize that they're*
19 *there, and how do we bridge those gaps. And that's really where our*
20 *activation now is because we know the patients are there.*

21
22 *We know they're diagnosed with an echo, but they're not moving. And so*
23 *it's just a matter of tapping into those patients in the right way and getting*
24 *them accelerated through the system.*

25
26 *Defendant Zovighian:* What's fair to say, though, is in the past few years, we
27 have done many pilots, many initiatives. We have extracted so many
28 learnings. ***What we are doing right now is scaling. We are scaling and***
29 ***spending. We are spending resources in Q4 last year, this year and the next***
30 ***few years. So, you are going to see more and more because we believe there***
31 ***are so many patients in need not receiving a treatment.***

32
33 ***2024 Proxy Statement***

34 98. On March 26, 2024, Edwards filed the 2024 Proxy Statement with the SEC.
35 Defendants Zovighian, Gallahue, Heisz, LaViolette, Loranger, Mussallem, Marsh,
36 Sequeira, and Valeriani solicited the 2024 Proxy Statement, which contained material
misstatements and omissions.

37 99. The 2024 Proxy Statement solicited shareholders to, *inter alia*: (1) reelect

1 Defendants Zovighian, Gallahue, Heisz, LaViolette, Loranger, Sequeira, and Valeriani, as
2 well as elect Defendant Davis for the first time, to the Board; (2) approve, on a non-binding
3 advisory basis, the compensation of Edwards's executive officers; (3) approve the 2024
4 Amended Stock Plan; and (4) ratify the appointment of PricewaterhouseCoopers LLP as
5 the Company's independent registered public accounting firm for the 2024 Fiscal Year.
6

7 100. The 2024 Proxy Statement explains that 2024 Amended Stock Plan would add
8 6,900,000 shares to the existing plan. As such, upon approval the 2024 Amended Stock
9 Plan would be comprised of 333,900,000 total shares. As of February 29, 2024, there were
10 15,814,148 shares available for grant under the plan. As such, following the approval of
11 the 2024 Amended Stock Plan, there would be a total of 22,714,148 shares available.
12 Further, approval of the 2024 Amended Stock Plan would extend the plan term from its
13 original end date of February 25, 2026, through February 21, 2034.

14 101. Regarding the Company's "Corporate Governance Guidelines," the 2024
15 Proxy Statement stated the following:

16 Our Board has adopted a set of Corporate Governance Guidelines to assist our
17 Board and its committees in performing their duties and serving the best
18 interests of our Company and its stockholders. The Corporate Governance
19 Guidelines cover topics including, but not limited to, director selection and
20 qualification, director responsibilities and operation of our Board, director
21 access to management and independent advisors, director compensation,
22 director orientation and continuing education, risk oversight, succession
planning, recoupment of incentive-based compensation and the annual
evaluations of our Board. Our Corporate Governance Guidelines are available
on our website at www.edwards.com under "Investors—Governance &
Sustainability—Governance—Governance Documents."

23 102. Regarding "Risk Oversight," the 2024 Proxy Statement stated the following,
24 in relevant part:

25 Effective risk oversight is a priority for our Board. Its role includes
26 understanding the critical risks in the business, including the severity and
27 immediacy of such risks, allocating the responsibilities for risk oversight
28 among the full Board and its committees, evaluating our Company's risk

1 management processes and facilitating open communication between
2 management and our directors.

3 While our Board oversees risk management, our Company's management is
4 charged with managing risk and bringing to our Board's attention emerging
5 risks as well as discussing the status of the long-term risks facing our
6 Company. Our strategic planning processes are designed to facilitate the
7 identification and management of such risks and ensure regular
8 communication with our Board and its committees. Our Board, in its full
9 composition and working through its committees, proactively participates in
10 the oversight of management's actions. At each regularly scheduled Board
11 meeting, and at least once per quarter, our Company's management provides
12 the full Board with an analysis and assessment of the key risks facing our
13 Company. The Chairman of the Board and the Chairpersons of our two
14 committees review and approve the agendas for, and information provided in,
15 such meetings, and call for additional meetings or executive sessions of our
16 Board or its committees to discuss risk-related topics as they may,
17 individually or collectively, determine necessary or appropriate. Our Board
18 also regularly engages with outside advisors and experts as it deems
appropriate from time to time to evaluate and anticipate current key risk areas
and consider strategies to respond. These advisors and experts provide
valuable information, including clinicians' perspectives, and best practices,
landscape overview, industry trends and peer data in areas such as the global
regulatory environment, governance, compensation, global operations and
corporate impact, to facilitate our Board's fulsome review and discussion of
these risk areas with the management team, which then informs action and
strategy.

19 103. Defendants Zovighian, Gallahue, Heisz, LaViolette, Loranger, Mussallem,
20 Marsh, Sequeira, and Valeriani caused the 2024 Proxy Statement to be false and misleading
21 by failing to disclose, *inter alia*, that: (1) the Individual Defendants indicated they had
22 reliable information regarding the Company's projected revenue and anticipated growth;
23 (2) in so doing, the Individual Defendants underplayed the risks associated with seasonality
24 and macroeconomic fluctuations; (3) the Individual Defendants' model relied too heavily
25 or otherwise overemphasized hospitals' desires to continue utilizing TAVR over newer,
26 more innovative therapies; (4) as a result, there was a significant risk that TAVR's growth
27 would decelerate; (5) the Individual Defendants were improperly interested in increasing

1 their future compensation by seeking shareholder approval of the 2024 Amended Stock
2 Plan; and (6) the Company lacked internal controls. As a result of the foregoing, the
3 Company's public statements were materially false and misleading and/or lacked a
4 reasonable basis at all relevant times.

5 104. The 2024 Proxy Statement also was false and misleading because it failed to
6 disclose that: (1) though the Company claimed its officers and directors adhered to the
7 Business Standards, the Individual Defendants violated these policies either without
8 waivers or without such waivers being disclosed; and (2) contrary to the 2024 Proxy
9 Statement's descriptions of the Board's and its committees' risk oversight functions, the
10 Board and its committees were not adequately exercising these functions and were causing
11 or permitting the Company to issue false and misleading statements.

12 105. As a result of Defendants Zovighian, Gallahue, Heisz, LaViolette, Loranger,
13 Mussallem, Marsh, Sequeira, and Valeriani causing the 2024 Proxy Statement to be false
14 and misleading, shareholders voted, *inter alia*, to: (1) reelect Defendants Zovighian,
15 Gallahue, Heisz, LaViolette, Loranger, Sequeira, and Valeriani, as well as elect Defendant
16 Davis for the first time, to the Board,³ thereby allowing them to continue breaching their
17 fiduciary duties to the Company; (2) approve, on a non-binding advisory basis, the
18 compensation of Edwards's executive officers; (3) approve the 2024 Amended Stock Plan;
19 and (4) ratify the appointment of PricewaterhouseCoopers LLP as the Company's
20 independent registered public accounting firm for the 2024 Fiscal Year.

21 106. As a result of the shareholders approving the 2024 Amended Stock Plan, an
22 additional 6,900,000 shares were made available for disbursement, allowing for a total of
23 15,814,148 shares. Additionally, the term of the 2024 Amended Stock Plan was extended

24
25 ³ Defendant Mussallem informed the Board that he did not intend to stand for reelection
26 on March 26, 2024. Similarly, Defendant Marsh had reached the mandatory retirement
27 age and was therefore unable to run for re-election in 2024. See Edwards Lifesciences
Corporation, Form 8-K, filed March 26, 2024.

28 <https://www.sec.gov/ix?doc=/Archives/edgar/data/0001099800/000109980024000031/e-w-20240326.htm>

1 from expiring on February 25, 2026, through February 21, 2034 As such, the Individual
2 Defendants continue to receive material personal benefits in the form of stock awards and
3 will continue to receive material personal benefits in the form of stock awards pursuant to
4 the 2024 Amended Stock Plan in the future.

5 ***April 25, 2024 Press Release***

6 107. On April 25, 2024, the Company issued a press release announcing its
7 financial results for the first quarter of the 2024 Fiscal Year (the “Q1 2024 Earnings
8 Release”). The Q1 2024 Earnings Release announced that “Q1 TAVR sales grew 6%;
9 constant currency sales grew 8% adjusted for billing days.”

10 ***April 25, 2024 Earnings Call***

11 108. That same day, the Company hosted an earnings call with investors and
12 analysts to discuss the first quarter results (the “Q1 2024 Earnings Call”). During his
13 scripted remarks, Defendant Zovighian explained the slow growth of the TAVR during the
14 quarter, stating:

15 Now, I will provide some additional detail on Q1 results, by product group.
16 In TAVR, first quarter global sales of \$1 billion increased 8%, year-over-year,
17 when adjusted for billing days. Q1 marked the first quarter that Edwards
18 TAVR sales exceeded \$1 billion, an exciting milestone for our team and a
19 testament to clinicians’ confidence in our leading technology. Performance
was driven by growth in the U.S. and Japan, Edward's global competitive
position, and selling prices were both stable.

20 In the U.S., our year-over-year first quarter TAVR sales growth rate was
21 higher than our global constant currency growth rate. We estimate total
22 procedure growth was comparable. Procedure volumes increased, as the
23 quarter progressed.

24 We remain pleased with the continued performance of our best-in-class
25 TAVR platform, SAPIEN 3 Ultra RESILIA, which builds on Edwards long-
26 standing leadership in tissue technology and durability. This innovative
27 technology now makes up the majority of our sales in the U.S. This platform
28 is supported by the robust real world data for more than 10,000 patients in the
TVT Registry that demonstrated excellent outcomes, across hundreds of
centers.

1 109. Discussing the TAVR's growth outside of the United States, Defendant
2 Zovighian explained:

3 Outside of the U.S., in the first quarter, our constant currency TAVR sales
4 growth was slightly below our global TAVR growth. Strong growth in Japan
5 and the rest of the world was partially offset by slower than expected growth
in Europe.

6 In Europe, our results were softer than expected in Q1. But we expect full year
7 2024 performance to normalize. We are actively preparing for the launch of
8 SAPIEN 3 Ultra RESILIA in Europe, and we anticipate introducing the
technology into the European market in Q2.

9 In Japan, we continue to see strong TAVR adoption driven by SAPIEN 3 Ultra
10 RESILIA. We believe AS remains a significantly undertreated disease among
11 the substantial elderly population and continue to focus on expanding the
12 ability of an evidence supporting this therapy.

13 110. Defendant Zovighian continued, exuding confidence in the TAVR growth for
the future, stating:

14 In closing, we are confident that Edwards is positioned for healthy and
15 sustainable TAVR growth well into the future, driven by our development of
16 differentiated TAVR technology, our deep commitment to advancing patient
17 care through high-quality clinical evidence and our investment in patient
activation initiatives.

18 Importantly, we are proud of our groundbreaking research into the treatment
19 of AS through our early TAVR and PROGRESS trial, which could,
20 fundamentally, change how AS patients are treated.

21 We remain confident in our full year TAVR sales growth of 8% to 10%. We
22 expect higher yearover-year second half growth rate than in the first and
23 second quarter.

24 111. Later, during the question-and-answer session of the Q1 2024 Earnings Call,
analysts asked a number of questions pertaining to the TAVR. One JPMorgan analyst asked
what the Company expected in terms of TAVR growth for the remainder of the year, to
which Defendants Zovighian and Wood responded:

25 *Robert Justin Marcus – JPMorgan Chase & Co.:* I caught the comments that
26 the U.S. TAVR grew faster than the global organic TAVR growth rate and

1 that procedure has accelerated, throughout the quarter. So, how are you
2 thinking about TAVR growth for the rest of the year? And do you feel like the
3 U.S. has finally recovered after some of the setbacks you saw during the
4 disruptive years of COVID? Thanks a lot.

5 *Defendant Zovighian:* Thanks, Robbie. Let me start and again, I will ask Larry
6 to add some insights here. So we knew, when we put together our guidance
7 for the year, the TAVR guidance 8% to 10%, we knew that the growth will
8 ramp throughout the year and that Q1 will be our lowest growth quarter. So
9 we feel confident about our 8% to 10%. We feel confident about what's
10 happening in the U.S., our share and price are stable. So we feel good about
11 all of that. Larry, you want to add anything?

12 *Defendant Wood:* Yeah. I don't have a lot to add. We saw good progression
13 throughout the quarter. It's always a little slow in January as we come out of
14 the break, but we are pleased with how the quarter went overall, and we
15 remain excited about the year. We have a lot of activities on patient activation.
16 We have a huge data set coming out of TCT that I think all of us are going to
17 be excited to see what that says, what those data say and how they inform the
18 field. *And so, I continue to believe we have a long runway long-term with
19 TAVR, and it is good to see the U.S. kind of put COVID, I think, finally in
20 the rearview mirror, and we can just focus on accelerating patient care.*

21 112. In response to another question from a Bank of America analyst regarding
22 TAVR's growth in Europe, Defendant Wood responded:

23 *Travis Lee Steed – BofA Securities:* Maybe on TAVR again, curious why
24 European growth was lower than expected? And then on the billing days, were
25 those U.S. or OUS and did those come back in any quarter?

26 *Defendant Wood:* Yeah, thanks. *Yeah, overall, we felt good about the
27 quarter, and we just talked about the U.S. We saw a lot of strength in Japan,
28 but Europe was--it grew year-over-year and it grew sequentially, and we lost
29 a couple of billing days. But even with that, we were a little bit disappointed
30 with our overall growth in Europe.*

31 We saw some pretty aggressive pricing from competitors that I think led to
32 some trialing. But we're really excited that we're launching S3UR that actually
33 starts this month, and we're excited to bring that technology to Europe, *and*
34 *we expect these to normalize, throughout the course of the year.*

35 113. In a follow-up question by the same analyst regarding how the Company has

1 driven growth, Defendants Wood and Zovighian responded:

2 *Steed*: All right. That's helpful. And then on TAVR and some of the things
3 you've been doing with egnite and kind of helping drive center growth and
4 diagnosis. Curious to see how that's going and at what point do you start to
5 kind of scale those programs out and an impact on, see the impact on TAVR
growth?

6 *Defendant Wood*: Yeah. ***We have a lot of patient activation activities where
there's a lot of work that we do.*** We have multiple fronts, and egnite is just
7 one part of our strategy there. But we're excited about what these technologies
8 can do. ***And there are so many patients, if you look at the Thieme and
(inaudible) publication, and I know he's spoken to you guys before, there's
just a lot of patients upstream that aren't moving through the system at the
speed in which they should.*** And I think there's a patient identification aspect,
9
10 there's a referral aspect.

11 So we have multiple work streams working on this. But I think the
12 appreciation and understanding for the undertreatment of aortic stenosis is
13 growing. And I think as that grows and people start to understand the
14 magnitude of the problem, I think it gives more opportunity for our patient
15 activation strategy to take hold.

16 *Defendant Zovighian*: And maybe in addition, Larry, I'm very proud about
17 what we are doing. We are the only one, basically, having a deep commitment
18 to advancing science for AS patients through the progress and early TAVR
19 trial. ***So this is truly our commitment, but we feel that there is a ton of
potential, especially our underdiagnosed, undertreated, and we are
committed to offer treatment for these patients. So as a company, very proud
about how we do all of this.***

20 114. In response to a question from a Wells Fargo analyst regarding the expected
21 TAVR growth acceleration, Defendant Wood stated:

22 *Lawrence Biegelsen – Wells Fargo Securities, LLC*: I just wanted on TAVR,
23 I wanted to confirm, Bernard said that Q2 TAVR growth will be better than
24 Q1, in response to Robbie's question. And why do you expect TAVR growth
25 to accelerate in the second half, and how are you guys factoring in the SMART
26 trial results? And I have one follow-up.

27 *Defendant Wood*: Yeah, we do expect to have procedures to ramp. That's
28 always been a part of our plan, and so we continue to expect that to happen.

1 And I think it's a lot of things, Larry, I think it's a lot of our patient activation
2 work. But it's also just the market continues to improve, and ***we're very pleased with where we finished Q4, last year.***
3

4 ***We were happy with the ramp in Q1. So I think we do expect to see an increase in Q2 over Q1. But even with that, we expect the second half to have a higher growth rate than the first half. So I think that that's good.***
5

6 115. In response to a question from a Barclays analyst regarding the activity levels
7 in the Company's major centers, Defendant Zovighian responded:

8 *Matthew Stephan Miksic – Barclays Bank PLC:* So just one question on sort
9 of TAVR and transcatheter valve growth, and I'll just keep it to one. If you could maybe talk a little bit about the launch of EVOQUE and the activity that
10 that drives in some of your major centers. And I guess how you're--you and the team in the field is kind of managing those activity levels or the bandwidth
11 of those centers versus the continuing volumes that they perform in TAVR.

12 Just maybe any color or thoughts on how that might play into the total
13 transcatheter business?

14 * * *

15 *Defendant Zovighian:* ***What it is fair to say is that, so far, we have not faced a big challenge in terms of centers having a lack of capacity to be able to treat the patients, whether TAVR patients or EVOQUE patients.***
16

17 116. In response to an RBC Capital Markets analyst's question regarding potential
18 drivers to get growth to at least 10%, Defendant Ullem responded:

19 *Shagun Singh Chadha – RBC Capital Markets:* It just sounds like U.S. TAVR
20 growth was high-single digits. Is that fair? Was it about 10%? And other
21 drivers that can get you to consistent double-digit growth in the foreseeable
22 future, just what's your confidence there?

23 * * *

24 *Defendant Ullem:* Yeah. I'll take the first part of that about U.S. TAVR
25 growth. We try not to be too specific about breaking down every region. But what we can say is that TAVR in the U.S. grew faster than our global
26 underlying growth rate for TAVR in the first quarter. Larry, do you want to
27 talk about the other pieces?

28 117. In his closing remarks on the Q1 2024 Earnings Call, Defendant Zovighian

1 acknowledged that “TAVR for sure, it is the largest business for us. It's still our number
2 one focus. TAVR has a lot of growth potential.”

3 ***June 5, 2024 Jeffries Conference***

4 118. On June 5, 2024, Defendant Ullem represented the Company in an interview-
5 style presentation during the Jeffries 2024 Global Healthcare Conference. During the
6 presentation, Defendant Ullem discussed TAVR’s impact on the Company’s guidance for
7 the remainder of the 2024 Fiscal Year, stating:

8 *Matthew Charles Taylor – Jeffries LLC:* So let's start with TAVR. Could you
9 talk a little bit about the TAVR trends in Q1? I guess you grew a little over
10 6%, about 7%. And talked about some trialing in Europe and some pricing
pressure there.

11 So I guess, could you give us an overview on what's happening, if there's any
12 update in Q2? And then overall, how do you expect the TAVR market to grow
13 and your growth to be within that?

14 *Defendant Ullem:* Yes. So yes, ***TAVR, we started out in the first quarter with
lower year-over-year growth rate than we expect for the full year.*** Our
15 guidance for TAVR for the year is 8% to 10%. ***We always knew that the first
half of the year was going to be a lower year-over-year growth environment
than the second half of the year. That's been our plan, and we saw that in
the first quarter again.***

16 Just breaking it down between the 4 areas of the world where we focus our
17 attention, U.S. grew faster than the OUS business in the first quarter. Japan
18 was our fastest big growing region in the first quarter. In Japan, we saw some
19 competitive pressure last year that abated in the second half of last year, and
20 we're back to more of a normalized growth curve in Japan. ***In Europe, we
were surprised a little bit in the first quarter by some of the competitive
trailing that we saw. We expect the European environment though to
normalize as we get later into 2024.***

21 ***And then the Rest of World where, today, we're in TAVR in over 60
countries. And so there are big growth opportunities in other areas of the
world, and that's been a pretty exciting area for us in 2024, and we think it
will be in '25 and beyond.***

1 Overall, the business is performing well. There's still an environment now
2 where around 13% of patients who have aortic stenosis, severe aortic stenosis
3 get treated today. And it's a remarkably low treatment rate, especially relative
4 to other diseases with a high mortality rate like severe aortic stenosis, and it
5 *gives us confidence that we should keep investing in this opportunity.*

6 In fact, we just finished enrollment in an important clinical trial studying
7 aortic stenosis in patients who just have a moderate form of the disease, where
8 it has not progressed yet to severe. And we think there's a real opportunity to
9 help patients who need earlier intervention to get their valve replaced and
10 today are not on indication to do so with TAVR.

11 There's another trial that's actually reading out later this year at the TCT
12 Conference, studying patients who have severe aortic stenosis without
13 symptoms. And if the trial shows what we think it will, it will be an important
14 opportunity to make this therapy available to patients who have this deadly
15 disease, but who did not get screened for care because they don't have
16 symptoms today.

17 So those are some of the factors that are underlying our current performance
18 and what we think are going to benefit our longer-term growth trends as well.

19 119. The statements referenced in ¶¶85-97, 107-118 above were materially false
20 and misleading when made because they failed to disclose material adverse facts about the
21 Company's business, operations, and prospects. Specifically, the identified statements
22 failed to disclose that: (1) the Individual Defendants indicated they had reliable information
23 regarding the Company's projected revenue and anticipated growth; (2) in so doing, the
24 Individual Defendants underplayed the risks associated with seasonality and
25 macroeconomic fluctuations; (3) the Individual Defendants' model relied too heavily or
26 otherwise overemphasized hospitals' desires to continue utilizing TAVR over newer, more
27 innovative therapies; (4) as a result, there was a significant risk that TAVR's growth would
28 decelerate; (5) the Individual Defendants were improperly interested in increasing their
 future compensation by seeking shareholder approval of the 2024 Amended Stock Plan;
 and (6) the Company lacked internal controls. As a result of the foregoing, the Company's
 public statements were materially false and misleading and/or lacked a reasonable basis at

1 all relevant times.
2

The Truth Emerges

July 24, 2024 Press Release

5 120. The truth emerged on July 24, 2024 when the Company issued the Q2 2024
6 Earnings Release. The Q2 2024 Earnings Release disclosed disappointing TAVR results
7 that came in below expectations, with the Company lowering its projections for the full-
8 year. The Q2 2024 Earnings Release stated, *inter alia*:

Highlights and Outlook

- 10 • Q2 sales grew 7%; constant currency sales grew 8%
- 11 • ***Q2 TAVR sales grew 5%; constant currency sales grew 6%***
- 12 • Q2 TMTT sales grew 75%; increasing contribution to Edwards' growth
- 13 • Q2 EPS of \$0.61; adjusted1 EPS of \$0.70
- 14 • Significant TAVR and TMTT clinical evidence to be presented at TCT
15 in October 2024
- 16 • Positive EVOQUE introduction with excellent patient outcomes; NCD
17 process on track
- 18 • Critical Care sale expected to close late Q3 2024
- 19 • Expect full-year 2024 Edwards sales growth of 8 to 10%; ***lowering***
20 ***TAVR guidance to 5 to 7% from 8 to 10%***; increasing TMTT guidance
21 to the higher end of \$320 to \$340 million

22 121. The Q2 2024 Earnings Release also quoted Defendant Zovighian, who
23 explained the results as “Second quarter total company sales growth of 8 percent reflected
24 strong contributions from our rapidly growing TMTT product group, ***offset by lower-than-***
25 ***expected growth in TAVR.***”

26 122. In discussing the TAVR-specific results, the Q2 2024 Earnings Release stated,
27 *inter alia*:

1 **Transcatheter Aortic Valve Replacement (TAVR)**

2 In the second quarter, ***the company reported TAVR sales of \$1.0 billion, which grew 5%, or 6% on a constant currency basis.*** Edwards' competitive
3 position did not meaningfully change globally, ***although the company experienced some regional pressures,*** and pricing was maintained.
4

5 Edwards remains pleased with the performance of its SAPIEN 3 Ultra
6 RESILIA platform, which is the leading platform in the U.S. and Japan. In the
7 second quarter, Edwards began the introduction of the SAPIEN 3 Ultra
8 RESILIA valve in Europe. The RESILIA tissue's anticalcification technology
9 is designed to address one of the primary causes of reintervention following
10 heart valve replacement and provides the potential to extend the durability of
the valve.

11 ***July 24, 2024 Earnings Call***

123. That same day, the Company hosted an earnings call with investors and
13 analysts to discuss the second quarter results (the “Q2 2024 Earnings Call”). On the Q2
14 20242 Earnings Call, Defendant Zovighian addressed the elephant in the room that was the
15 disappointing guidance, stating:

16 ***In the US, our year-over-year second quarter TAVR sales growth was slightly below our global constant currency-growth rate.*** We believe our US
17 competitive position was largely unchanged. ***Second quarter US TAVR sales grew slower than expected.*** The continued growth and expansion of structural
18 heart therapies, including newly approved tricuspid therapies and other fast-
19 growing structural heart therapies put pressure on hospital workflows, which
20 impacted TAVR. These pressures were also observed in the recent spike in
emergent TAVR cases, as reflected in claims data.

21 As centers adopt these new therapies and they become part of extended
22 processes, we expect this will stabilize.

23 124. Defendant Zovighian continued, announcing the new (and lower) expected
24 TAVR growth rates, stating:

25 ***In closing, we now anticipate second half TAVR sales growth similar to the first half year-over-year growth rate, a 5% to 7% full-year growth rate versus previously guidance of 8% to 10%.*** This equate to full-year global TAVR
26 sales of \$4 billion to \$4.2 billion.
27

125. In attempting to further explain the reasoning behind the disappointing guidance, Defendant Zovighian pointed to the Company's recent acquisitions, stating:

Earlier this month, we announced the acquisition of JenaValve. JenaValve early-stage technology will add to our growing pipeline of innovative therapy in TMTT and we expect to close the acquisition later this year. We further expect that JenaValve technology, combined with Edwards expertise in mitral disease, will enhance the company TMVR technologies to address large unmet structural heart (ph) patient needs and support sustainable long-term growth. Based on the first half 2024 momentum and the ongoing global adoption of our differentiated technology PASCAL and EVOQUE we are increasing full-year sales guidance for TMTT to the higher end of our previous \$320 million to \$340 million range.

* * *

Turning now to the strategic acquisition of JenaValve and Endotronix. These acquisitions provide an expanded opportunity in new therapeutic areas to address the unmet needs of AR and heart failure patients around the world. Furthermore, the acquisition reflects our deep commitment to advancing patient care through our unique strategy and reinforce our confidence in Edwards sustainable long-term growth. Starting with JenaValve, a pioneer in the transcatheter treatment of AR, a deadly disease that impacts more than 100,000 patients in the US alone and is largely untreated today.

Edwards anticipate US FDA approval of the JenaValve Trilogy Heart Valve System in late 2025, which will represent the first approved therapy for patient suffering from AR. Edwards will invest to accelerate development of this novel technology to enable earlier patient access. As the pioneers in valve innovation, we believe we are best positioned to lead this next frontier of aortic valve disease treatment. We expect this to be the beginning of a long-term iterative strategy similar to TAVR.

Turning to Endotronix. Edwards made its first investment in the company in 2016, so we are very familiar with the technology, the opportunity and the employees. Many structural heart patients Edwards serves today also suffer from heart failure, with limited options. This acquisition will expand Edwards structural heart portfolio into a new therapeutic area to address the large unmet needs of patients suffering from heart failure, which we believe has a significant long-term growth opportunity. Last month, Endotronix received FDA approval for Cordella (ph), an implantable preliminary artillary pressure sensor that directly measure the leading indicator of congestion following the

1 publication of a successful US pivotal trial.

2 We are pleased to enter the structural heart therapeutic area with innovation,
3 world-class science, and clinical evidence to provide access to life-saving
4 technologies for patients around the world. We anticipate this investment will
5 strengthen its leadership in structural heart innovation and represent long-term
6 growth opportunity. Minimal revenue contribution from JenaValve and
7 Endotronix is expected to begin late in 2025.

8 126. During the question-and-answer session of the call, analysts looked to shed a
9 little more light on the negative guidance. In response to one JPMorgan analyst's question
10 regarding the underlying growth of the TAVR market, Defendant Wood responded:

11 *Robert Justin Marcus – JP Morgan Chase:* Two from me. Maybe first, you
12 talked about it in the script, but I was hoping you could give a little more,
13 TAVR has clearly come in below your initial expectations for the year. The
14 guidance has moved down. The US is slowing. OUS is facing pressure. We
15 saw two of your smaller competitors, but still competitors, see pretty nice
16 growth sequentially and year-over-year, so their TAVR is taking more in
Europe and outside the US, Japan. How are you thinking just about the
underlying growth rate of the TAVR market? And I appreciate it's a huge
opportunity and it's still a lot to conquer in the future, but in, let's call it the
short to medium term, how are you thinking about the overall market growth?
And is there anything you can do to help accelerate it?

17 *Defendant Wood:* Yeah. Thanks, Robbie. Well, obviously, ***we expected
growth rate to be higher in Q2 than it was.*** We had a slow start in Q1, but we
18 were exiting March and we felt good about where we were. So ***this did come
as a surprise. I think when we reflect back on it, and we look more deeply
at it, you have to think about all the things that have shown up that are
going to the same structural heart team at all of these hospitals.***

22 We're seeing rapid growth in mitral repair. ***We're seeing a lot of growth in
other procedures, and we had two new therapy approvals recently in the
tricuspid space.*** And I think a little bit we looked at the procedure volumes
23 and the hospitals have shown a pretty good job of being able to handle these
24 things. ***We probably underestimated the burden of even starting these new
programs, even preparing to start these new programs, because you have to
screen the patients early on. There's a lot of learning, screen failures, all of
25 those things, and I think it's just tasking the teams.***

1 Now, in terms of things we can do to help, *there are certainly things we can*
2 *do to help. We can do a lot of imaging workups and take some of the load*
3 *off the team. We can do device prep. We can come in with our benchmark*
4 *program and teach them efficiencies and do those things.* But once a
5 program has been optimized, that it really does come down to the hospital to
add another team or add additional bays and do those sorts of things. So there
are some things we can do, but we can't do everything.

6 I think the other thing is, *I think highlighting this for the clinicians and we're*
7 *very confident, this isn't some slowdown because there's a lack of patients.* We didn't see any of the fundamentals change in terms of new data that was
8 concerning or any of these things. *I think it's just a matter of the workflow*
9 *right now. And we need to be able to engage with hospitals, but two*
10 *important things we saw, is we saw an increase in time from CT to*
11 *procedure, which indicates patients are waiting longer. And the other thing*
12 *that we saw was a sharp increase in the number of cases being coded as*
13 *emergent versus routine, and I think that speaks to these patients waiting in*
14 *the queue as these workflow issues sort out. So I think hospitals will certainly*
15 *do that in time. These patients don't wait well, and we know that there's a lot*
16 *of them, but we're going to have to continue to work through that with the*
17 *hospitals.*

127. Defendant Zovighian added on to these sentiments, mentioning:

128. Yeah. So let me add on what Larry said. *To be fair, we are contributing a*
129 *little bit on this pressure. At the same time, we are benefiting if you look at*
130 *the TMTT growth in the quarter. So we are contributing and benefiting at*
131 *the same time.* Now, big picture. We have seen this picture in the past. Don't
132 you think? We have seen hospital facing more to do, more technology to
133 adopt, to be trying on new technologies, and we are very good at scaling. We
134 are very good at learning. We are very good at adapting their workflows in
135 the cath lab, so we believe it is temporary. And we are also in it with this team,
136 with Larry partnering on this one, so we are fully focusing on this one, helping
137 every hospital. But we have faith the hospital are going to do that, like they
138 did it in the last 10 years.

139 128. The same analyst followed up, inquiring about the now more conservative
140 growth estimate. In response, Defendants Ullem and Zovighian stated:

141 *Marcus:* Great. And maybe a follow-up to that. Guidance implies roughly
142 stable TAVR first half into second half. I appreciate the need to be
143 conservative, but it sounds like some of the learnings you saw in second
144 quarter could possibly help in the back half of the year. Maybe just walk

1 through the thought process of the 5% to 7% TAVR guide and kind of what
2 you're baking into that? Thanks a lot.

3 *Defendant Ullem:* Yeah. I mean, it's pretty straightforward which is we're
4 baking into it similar market conditions. The year-over-year calculation is
5 pretty similar. ***Fourth quarter comp gets a little bit tougher, but we think
6 that all things considered, that 5% of the low end, 7% on the high end
captures the likely scenario for the second half combined with the first half
7 that we've already reported.***

8 *Defendant Zovighian:* We believe, to add on that one, we believe early TAVR,
9 TCT, it will be already almost the end of a quarter, Robbie. So TCT is in late
10 October, so we believe it will have a very minimal impact in Q4, so it is why
we didn't want to take too much risk here.

11 129. In response to a Bank of America analyst's question regarding what surprised
12 the Individual Defendants regarding the TAVR second quarter results, Defendant Wood
13 responded:

14 *Travis Lee Steed – BofA Securities:* I wanted to go back and circle back on
15 Robbie's question on TAVR. It feels like there's a little bit more of a change
16 here. Just three months ago, you thought TAVR was going to accelerate over
17 the course of the year. I thought the 8% to 10% at the beginning of the year
18 was supposed to be a conservative guide. So just want to understand, I hear
19 what you're saying on TMTT, but that's a small number of faction versus the
20 overall TAVR centers. So I don't know if there's anything else that you'd kind
of call out or kind of what surprised you on the TAVR line. I know there was
some of the European stuff and competition there that you called out last
quarter, just understanding kind of the full change and why you got the initial
TAVR guide wrong at the start of this year.

21 *Defendant Wood:* Yeah. Thanks, Travis. Yeah. When we exited Q1, we
22 thought we were on a good ramp, and we thought we were on a good pace,
23 and that's why reiterated guidance and we felt good about it, and ***we just didn't
see that play out in Q2 the way that we anticipated.*** And by no means do I
24 mean to say this is all Daveen's fault and it's all EVOQUE because that's not
25 accurate or fair when you look at the number of procedures. ***I think it's the
cumulative impact of all the things that have hit the structural heart teams
over the last year.***

26
27 And it's one of those things, you can always increase a little capacity, work a
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1 little harder, increase a little capacity, work a little bit harder, but then at some
2 point, you reach a breakpoint when it's simply too much. And the heaviest lift
3 for centers is starting a program and it's not just the procedure volume. It's all
4 that screening and all of the case reviews and all the interaction that just
5 consumes a lot of resources and a lot of time. And the training, they have to
6 go to training and observe cases, in many cases, and all of those sorts of things.
*And so, I think it's just the cumulative impact of those things that happen
over time.*

7 And we did see the slowdown more acutely in large centers and small centers,
8 which fits a little bit of the model as well in terms of the centers that are most
9 likely to be looking to start these new programs and are competitive about
10 that. And again, I said it earlier, but we did see a spike in emerging cases over
11 routine cases, and I think that fits what we're saying as well, but that's not
12 going to be sustainable for people. Emerging cases have more complications.
13 They don't have as good a patient outcomes and people will have longer
14 lengths of stay and that's going to adversely impact patients and the hospitals
15 themselves. *So I think people will have to adjust it over time and we're going
to have to work closely with them to help them do that.*

16 130. Lastly, in response to a Jeffries analyst's question regarding how long the
17 Company anticipated it would take to adjust, Defendants Wood and Zovighian responded:
18 *Matthew Charles Taylor – Jeffries LLC:* I guess I wanted to follow up on some
19 of your US TAVR commentary and the workflow angle, because I'd like to
20 understand better why you think it's showing up so acutely now, I guess, given
21 you're still in a limited rollout of EVOQUE. Is this an issue that's been
22 matriculating for a while and we're just seeing it more now? And could you
23 help us understand your history there? You talked about the impact on
24 coronaries. How long do you think it'll take for the hospital to adjust? Is this
25 a one quarter or a three-quarter issue? Does it take years? What kind of time
26 frame would you put on them adjusting to accommodate the additional
27 workflows?

28 *Defendant Wood:* Yeah. Thanks, Matt. The thing that I would say is, I guess
if I were to draw an analogy, if you had a factory and you saw demand for
your product going up, you can always add a little more hours and you always
have a little bit of excess capacity, and you can adjust to those things. *I think
there is just a point in time where you hit a wall, and it's harder to do those
things, and I think that's a little bit of what we saw here. It's the cumulative
effect of all of these things that have played out over time.* If you look at total
cath lab procedures for the structural heart team in the last three years, it's

probably close to double during that period of time, which is a lot of growth that these teams are having to absorb and they're having to adapt to, and I think it will take time.

And again, when you're starting these new programs, these new therapies, that's the heaviest lift part of it. And again, I think this gets corrected over time, and we'll work closely with the hospitals to do that. But we reflected that in our guidance and just wanted to be realistic and not be tone deaf to what's happened. But the same thing I'll tell you, is none of us are happy with the growth rate. None of us are happy adjusting guidance and we're going to be working as hard as we can, to do everything we can to restore the growth to where we think it should be.

Defendant Zovighian: And we are not happy as a company, the patients are not happy, the physician are not happy, the hospital are not happy, so we are fully aligned about it is a problem, we need to solve it. So it is why also we are confident here.

131. On this news, the Company's stock price fell \$27.25 per share, or 31.3%, from a closing price of \$86.95 per share on July 24, 2024 to close at \$59.70 per share on July 25, 2024.

REPURCHASES DURING THE RELEVANT PERIOD

132. During the Relevant Period, the Individual Defendants caused the Company to initiate repurchases of its common stock that substantially damaged the Company. In total, the Company spent an aggregate amount of approximately \$178 million to repurchase approximately 2,174,656 shares of its own common stock at artificially inflated prices from April 2024 through July 2024.

133. According to the Form 10-Q the Company filed with the SEC on July 31, 2024 for the quarterly period ended June 30, 2024 (the “Q2 2024 10-Q”), between April 1, 2024 and April 30, 2024, the Company repurchased 1,396,161 shares of its own common stock at an average price per share of approximately \$86.72, for a total cost to the Company of approximately \$121,075,082.

134. As the Company's stock was actually worth only \$59.70 per share, the price at closing on July 25, 2024, the Company overpaid by approximately \$37,724,270 for

1 repurchases of its own stock between April 1, 2024 and April 30, 2024.
2

3 135. According to the 2Q 2024 10-Q, between May 1, 2024 and May 31, 2024, the
4 Company repurchased 333,496 shares of its own common stock at an average price per
5 share of approximately \$86.72 per share, for a total cost to the Company of approximately
6 \$28,920,773.

7 136. As the Company's stock was actually worth only \$59.70 per share, the price
8 at closing on July 25, 2024, the Company overpaid by approximately \$9,011,062 for
9 repurchases of its own stock between May 1, 2024 and May 31, 2024.

10 137. According to the Form 10-Q the Company filed with the SEC on November
11 6, 2024 for the quarterly period ended September 30, 2024 (the "Q3 2024 10-Q"), between
12 July 1, 2024 and July 31, 2024, the Company repurchased 444,999 shares of its own
13 common stock at an average price per share of approximately \$62.91, for a total cost to the
14 Company of approximately \$27,994,887.

15 138. As the Company's stock was actually worth only \$59.70 per share, the price
16 at closing on July 25, 2024, the Company overpaid by approximately \$1,428,447 for
17 repurchases of its own stock between July 1, 2024 and July 31, 2024.

18 139. Thus, in total, during the Relevant Period, the Company overpaid for
19 repurchases of its own stock by approximately \$48.2 million.

DAMAGES TO EDWARDS

20 140. As a direct and proximate result of the Individual Defendants' conduct,
21 Edwards has lost and will continue to lose and expend many millions of dollars.

22 141. Such expenditures include, but are not limited to, legal fees, costs, and any
23 payments for resolution of or to satisfy a judgment associated with the Securities Class
24 Action, and amounts paid to outside lawyers, accountants, and investigators in connection
25 thereto.

26 142. Such expenditures also include, but are not limited to, fees, costs, and any
27 payments for resolution of or to satisfy judgments associated with any other lawsuits filed
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1 against the Company or the Individual Defendants based on the misconduct alleged herein,
2 and amounts paid to outside lawyers, accountants, and investigators in connection thereto.
3

4 143. Such expenditures will also include costs incurred in any internal
5 investigations pertaining to violations of law, costs incurred in defending any
6 investigations or legal actions taken against the Company due to its violations of law, and
7 payments of any fines or settlement amounts associated with the Company's violations.
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9 144. Such losses include the Company's overpayment of approximately \$48.2
10 million for repurchases of its own stock during the period when the Company's stock price
11 was artificially inflated due to the false and misleading statements discussed above.
12

13 145. Additionally, these expenditures include, but are not limited to, unjust
14 compensation, benefits, and other payments provided to the Individual Defendants who
15 breached their fiduciary duties to the Company.
16

17 146. As a direct and proximate result of the Individual Defendants' conduct,
18 Edwards has also suffered and will continue to suffer a loss of reputation and goodwill,
19 and a "liar's discount" that will plague the Company's stock in the future due to the
20 Company's and their misrepresentations.
21

DERIVATIVE ALLEGATIONS

22 147. Plaintiff brings this action derivatively and for the benefit of Edwards to
23 redress injuries suffered, and to be suffered, as a result of the Individual Defendants'
24 breaches of their fiduciary duties as directors and/or officers of Edwards, unjust
25 enrichment, abuse of control, gross mismanagement, waste of corporate assets, violations
26 of Sections 10(b), 20(a), and 14(a) of the Exchange Act, as well as for contribution under
27 Sections 10(b) and 21D of the Exchange Act.
28

148. Edwards is named solely as a nominal party in this action. This is not a
collusive action to confer jurisdiction on this Court that it would not otherwise have.

149. Plaintiff is, and has been at all relevant times, a shareholder of Edwards.
Plaintiff will adequately and fairly represent the interests of Edwards in enforcing and

1 prosecuting its rights, and, to that end, has retained competent counsel, experienced in
2 derivative litigation, to enforce and prosecute this action.
3

4 **DEMAND FUTILITY ALLEGATIONS**

5 150. Plaintiff incorporates by reference and realleges each and every allegation
6 stated above as if fully set forth herein.
7

8 151. A pre-suit demand on the Board is futile and, therefore, excused. When this
9 action was filed, Edwards's Board consisted of the following nine individuals: Defendants
10 Zovighian, Davis, Gallahue, Heisz, LaViolette, Loranger, Sequeira, and Valeriani (the
11 "Director-Defendants") and non-party David Feinberg (together with the Director-
12 Defendants, the "Directors"). Plaintiff needs only to allege demand futility as to five of the
13 nine Directors that were on the Board at the time this action was filed.
14

15 152. Demand is excused as to all of the Director-Defendants because each one of
16 them faces, individually and collectively, a substantial likelihood of liability as a result of
17 the scheme they engaged in knowingly or recklessly to make and/or cause the Company to
18 make false and misleading statements and omissions of material fact, while they caused
19 the Company to repurchase its own stock at artificially inflated prices. This renders the
20 Director-Defendants unable to impartially investigate the charges and decide whether to
21 pursue action against themselves and the other perpetrators of the scheme.
22

23 153. In complete abdication of their fiduciary duties, the Director-Defendants
24 either knowingly or recklessly caused or permitted Edwards to issue materially false and
25 misleading statements. Specifically, the Director-Defendants caused Edwards to issue false
26 and misleading statements which were intended to make Edwards appear more profitable
27 and attractive to investors. Moreover, the Director-Defendants caused the Company to fail
28 to maintain internal controls. As a result of the foregoing, the Director-Defendants
breached their fiduciary duties, face a substantial likelihood of liability, are not
disinterested, and demand upon them is futile, and thus excused.

154. Moreover, Defendants Zovighian, Gallahue, Heisz, LaViolette, Loranger,

1 Sequeira, and Valeriani solicited the 2024 Proxy Statement, which called for a shareholder
2 vote to, *inter alia*, reelect Defendants Zovighian, Gallahue, Heisz, LaViolette, Loranger,
3 Sequeira, and Valeriani, as well as elect Defendant Davis for the first time, to the Board,
4 allowing them to continue breaching their fiduciary duties to the Company.

5 155. In addition, the Defendants Zovighian, Gallahue, Heisz, LaViolette, Loranger,
6 Sequeira, and Valeriani caused the 2024 Proxy Statement to call for a shareholder vote to
7 approve the 2024 Amended Stock Plan, which made shares available to employees and
8 directors of the Company. The misrepresentations and omissions set forth herein were
9 material to shareholders in voting to approve the 2024 Amended Stock Plan, who would
10 not have approved the 2024 Amended Stock Plan, had they been informed about the
11 Individual Defendants' misconduct. Before the shareholders approved the 2024 Amended
12 Stock Plan at the annual meeting of stockholders of Edwards on May 7, 2024, there were
13 15,814,148 shares available under the then-existing plan, which would have terminated in
14 February 2026. After the shareholders approved the 2024 Amended Stock Plan, 6,900,000
15 additional shares were made available under the plan (plus the remaining shares from the
16 pre-existing plan) and the 2024 Amended Stock Plan was now effective until February
17 2034. For this reason, the Individual Defendants, including the Director-Defendants,
18 received material personal benefits they otherwise would not receive but for the issuance
19 of the false and misleading 2024 Proxy Statement and the shareholders approving the 2024
20 Amended Stock Plan pursuant to the 2024 Proxy Statement. As such, the Director-
21 Defendants face a substantial likelihood of liability and demand is futile as to them.

22 156. To date, Defendants Zovighian, Gallahue, and Heisz have received material
23 personal benefits from their insider sales as a result of the Individual Defendants' false and
24 misleading statements alleged herein. As a result of the false and misleading statements,
25 Defendant Zovighian profited by approximately \$755,538 during the Relevant Period,
26 Defendant Gallahue profited by approximately \$267,911 during the Relevant Period, and
27 Defendant Heisz profited by approximately \$609,991 during the Relevant Period.

1 157. Additional reasons that demand on Defendant Zovighian is futile follow.
2 Defendant Zovighian has been the Company's CEO and a director since May 2023.
3 Defendant Zovighian has been employed by the Company since 2015, most recently
4 working as the Corporate Vice President and General Manager for TMTT. The Company
5 provides Defendant Zovighian with his principal occupation for which he receives
6 handsome compensation. Thus, as the Company admits, he is a non-independent director.
7 Moreover, Defendant Zovighian solicited the 2024 Proxy Statement, which contained
8 material misrepresentations and omissions that led to the re-election Defendants Gallahue,
9 Heisz, LaViolette, Loranger, Sequeira, Valeriani, and himself, as well as elect Defendant
10 Davis for the first time, to the Board, allowing them to continue to breach their fiduciary
11 duties to the Company, as well as the approval of the 2024 Amended Stock Plan. As the
12 Company's highest officer, he conducted little, if any, oversight of the scheme to make
13 and/or cause the Company to make false and misleading statements, consciously
14 disregarded his duties to monitor such controls over reporting and engagement in the
15 scheme, and consciously disregarded his duties to protect corporate assets. In addition,
16 during the Relevant Period, he failed to correct the false and misleading statements alleged
17 herein and personally made many of the false and misleading statements alleged herein.
18 Further, Defendant Zovighian is a defendant in the Securities Class Action. Moreover,
19 under the 2024 Amended Stock Plan, Defendant Zovighian is eligible to receive stock
20 awards under the 2024 Amended Stock Plan, and will receive various amounts of stock
21 awards under the 2024 Amended Stock Plan in the future, thereby materially benefiting
22 from the adoption of the 2024 Amended Stock Plan. Moreover, Defendant Zovighian has
23 materially benefitted from the Individual Defendants' breaches of fiduciary duty alleged
24 herein, having made insider sales while the Company's stock price was artificially inflated
25 as a result of the false and misleading statements alleged herein, with personal proceeds of
26 approximately \$755,538. For these reasons, too, Defendant Zovighian breached his
27 fiduciary duties, faces a substantial likelihood of liability, is not independent or
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1 disinterested, and thus demand upon him is futile and, therefore, excused.
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3 158. Additional reasons that demand on Defendant Davis is futile follow.
4 Defendant Davis has served as a Company director since May 2024. Defendant Davis also
5 serves as a member of the Compensation and Governance Committee. As a trusted director,
6 she conducted little, if any, oversight of the scheme to make and/or cause the Company to
7 make false and misleading statements, consciously disregarded her duties to monitor such
8 controls over reporting and engagement in the scheme, and consciously disregarded her
9 duties to protect corporate assets. Moreover, under the 2024 Amended Stock Plan,
10 Defendant Davis is eligible to receive stock awards under the 2024 Amended Stock Plan,
11 and will receive various amounts of stock awards under the 2024 Amended Stock Plan in
12 the future, thereby materially benefiting from the adoption of the 2024 Amended Stock
13 Plan. For these reasons, too, Defendant Davis breached her fiduciary duties, faces a
14 substantial likelihood of liability, is not independent or disinterested, and thus demand
upon her is futile and, therefore, excused.

159. Additional reasons that demand on Defendant Gallahue is futile follow.
16 Defendant Gallahue has served as a Company director since 2015. Defendant Gallahue
17 also serves as a member of the Audit Committee. Moreover, Defendant Gallahue solicited
18 the 2024 Proxy Statement, which contained material misrepresentations and omissions that
19 led to the re-election Defendants Zovighian, Heisz, LaViolette, Loranger, Sequeira,
20 Valeriani, and himself, as well as elect Defendant Davis for the first time, to the Board,
21 allowing them to continue to breach their fiduciary duties to the Company, as well as the
22 approval of the 2024 Amended Stock Plan. As a trusted, long-time director, he conducted
23 little, if any, oversight of the scheme to make and/or cause the Company to make false and
24 misleading statements, consciously disregarded his duties to monitor such controls over
25 reporting and engagement in the scheme, and consciously disregarded his duties to protect
26 corporate assets. Moreover, under the 2024 Amended Stock Plan, Defendant Gallahue is
27 eligible to receive stock awards under the 2024 Amended Stock Plan, and will receive

1 various amounts of stock awards under the 2024 Amended Stock Plan in the future, thereby
2 materially benefiting from the adoption of the 2024 Amended Stock Plan. Moreover,
3 Defendant Gallahue has materially benefitted from the Individual Defendants' breaches of
4 fiduciary duty alleged herein, having made insider sales while the Company's stock price
5 was artificially inflated as a result of the false and misleading statements alleged herein,
6 with personal proceeds of approximately \$267,911. For these reasons, too, Defendant
7 Gallahue breached his fiduciary duties, faces a substantial likelihood of liability, is not
8 independent or disinterested, and thus demand upon him is futile and, therefore, excused.

9 160. Additional reasons that demand on Defendant Heisz is futile follow.
10 Defendant Heisz has served as a Company director since 2016. Defendant Heisz also serves
11 as the Chair of the Audit Committee. Moreover, Defendant Heisz solicited the 2024 Proxy
12 Statement, which contained material misrepresentations and omissions that led to the re-
13 election Defendants Zovighian, Gallahue, LaViolette, Loranger, Sequeira, Valeriani, and
14 herself, as well as elect Defendant Davis for the first time, to the Board, allowing them to
15 continue to breach their fiduciary duties to the Company, as well as the approval of the
16 2024 Amended Stock Plan. As a trusted, long-time director, she conducted little, if any,
17 oversight of the scheme to make and/or cause the Company to make false and misleading
18 statements, consciously disregarded her duties to monitor such controls over reporting and
19 engagement in the scheme, and consciously disregarded her duties to protect corporate
20 assets. Moreover, under the 2024 Amended Stock Plan, Defendant Heisz is eligible to
21 receive stock awards under the 2024 Amended Stock Plan, and will receive various
22 amounts of stock awards under the 2024 Amended Stock Plan in the future, thereby
23 materially benefiting from the adoption of the 2024 Amended Stock Plan. Moreover,
24 Defendant Heisz has materially benefitted from the Individual Defendants' breaches of
25 fiduciary duty alleged herein, having made insider sales while the Company's stock price
26 was artificially inflated as a result of the false and misleading statements alleged herein,
27 with personal proceeds of approximately \$609,991. For these reasons, too, Defendant
28

1 Heisz breached her fiduciary duties, faces a substantial likelihood of liability, is not
2 independent or disinterested, and thus demand upon her is futile and, therefore, excused.
3

4 161. Additional reasons that demand on Defendant LaViolette is futile follow.
5 Defendant LaViolette has served as a Company director since 2020. Defendant LaViolette
6 also serves as the Chair of the Compensation and Governance Committee. Moreover,
7 Defendant LaViolette solicited the 2024 Proxy Statement, which contained material
8 misrepresentations and omissions that led to the re-election Defendants Zovighian,
9 Gallahue, Heisz, Loranger, Sequeira, Valeriani, and himself, as well as elect Defendant
10 Davis for the first time, to the Board, allowing them to continue to breach their fiduciary
11 duties to the Company, as well as the approval of the 2024 Amended Stock Plan. As a
12 trusted, long-time director, he conducted little, if any, oversight of the scheme to make
13 and/or cause the Company to make false and misleading statements, consciously
14 disregarded his duties to monitor such controls over reporting and engagement in the
15 scheme, and consciously disregarded his duties to protect corporate assets. Moreover,
16 under the 2024 Amended Stock Plan, Defendant LaViolette is eligible to receive stock
17 awards under the 2024 Amended Stock Plan, and will receive various amounts of stock
18 awards under the 2024 Amended Stock Plan in the future, thereby materially benefiting
19 from the adoption of the 2024 Amended Stock Plan. For these reasons, too, Defendant
20 LaViolette breached his fiduciary duties, faces a substantial likelihood of liability, is not
21 independent or disinterested, and thus demand upon him is futile and, therefore, excused.
22

23 162. Additional reasons that demand on Defendant Loranger is futile follow.
24 Defendant Loranger has served as a Company director since 2016. Defendant Loranger
25 also serves as a member of the Audit Committee. Moreover, Defendant Loranger solicited
26 the 2024 Proxy Statement, which contained material misrepresentations and omissions that
27 led to the re-election Defendants Zovighian, Gallahue, Heisz, LaViolette, Sequeira,
28 Valeriani, and himself, as well as elect Defendant Davis for the first time, to the Board,
allowing them to continue to breach their fiduciary duties to the Company, as well as the

1 approval of the 2024 Amended Stock Plan. As a trusted, long-time director, he conducted
2 little, if any, oversight of the scheme to make and/or cause the Company to make false and
3 misleading statements, consciously disregarded his duties to monitor such controls over
4 reporting and engagement in the scheme, and consciously disregarded his duties to protect
5 corporate assets. Moreover, under the 2024 Amended Stock Plan, Defendant Loranger is
6 eligible to receive stock awards under the 2024 Amended Stock Plan, and will receive
7 various amounts of stock awards under the 2024 Amended Stock Plan in the future, thereby
8 materially benefiting from the adoption of the 2024 Amended Stock Plan. For these
9 reasons, too, Defendant Loranger breached his fiduciary duties, faces a substantial
10 likelihood of liability, is not independent or disinterested, and thus demand upon him is
11 futile and, therefore, excused.

12 163. Additional reasons that demand on Defendant Sequeira is futile follow.
13 Defendant Sequeira has served as a Company director since 2020. Defendant Sequeira also
14 serves as a member of the Audit Committee. Moreover, Defendant Sequeira solicited the
15 2024 Proxy Statement, which contained material misrepresentations and omissions that led
16 to the re-election Defendants Zovighian, Gallahue, Heisz, LaViolette, Loranger, Valeriani,
17 and herself, as well as elect Defendant Davis for the first time, to the Board, allowing them
18 to continue to breach their fiduciary duties to the Company, as well as the approval of the
19 2024 Amended Stock Plan. As a trusted, long-time director, she conducted little, if any,
20 oversight of the scheme to make and/or cause the Company to make false and misleading
21 statements, consciously disregarded her duties to monitor such controls over reporting and
22 engagement in the scheme, and consciously disregarded her duties to protect corporate
23 assets. Moreover, under the 2024 Amended Stock Plan, Defendant Sequeira is eligible to
24 receive stock awards under the 2024 Amended Stock Plan, and will receive various
25 amounts of stock awards under the 2024 Amended Stock Plan in the future, thereby
26 materially benefiting from the adoption of the 2024 Amended Stock Plan. For these
27 reasons, too, Defendant Sequeira breached her fiduciary duties, faces a substantial
28

1 likelihood of liability, is not independent or disinterested, and thus demand upon her is
2 futile and, therefore, excused.

3 164. Additional reasons that demand on Defendant Valeriani is futile follow.
4 Defendant Valeriani has served as a Company director since 2014, and as the Board Chair
5 since May 2024. Defendant Valeriani also serves as a member of the Compensation and
6 Governance Committee. Moreover, Defendant Valeriani solicited the 2024 Proxy
7 Statement, which contained material misrepresentations and omissions that led to the re-
8 election Defendants Zovighian, Gallahue, Heisz, LaViolette, Loranger, Sequeira, and
9 himself, as well as elect Defendant Davis for the first time, to the Board, allowing them to
10 continue to breach their fiduciary duties to the Company, as well as the approval of the
11 2024 Amended Stock Plan. As a trusted, long-time director and the Chair of the Board, he
12 conducted little, if any, oversight of the scheme to make and/or cause the Company to make
13 false and misleading statements, consciously disregarded his duties to monitor such
14 controls over reporting and engagement in the scheme, and consciously disregarded his
15 duties to protect corporate assets. Moreover, under the 2024 Amended Stock Plan,
16 Defendant Valeriani is eligible to receive stock awards under the 2024 Amended Stock
17 Plan, and will receive various amounts of stock awards under the 2024 Amended Stock
18 Plan in the future, thereby materially benefiting from the adoption of the 2024 Amended
19 Stock Plan. For these reasons, too, Defendant Valeriani breached his fiduciary duties, faces
20 a substantial likelihood of liability, is not independent or disinterested, and thus demand
21 upon him is futile and, therefore, excused.

22 165. Additional reasons that demand on the Board is futile follow.

23 166. Defendants Heisz (as Chair), Gallahue, and Sequeira served as members of
24 the Audit Committee at all relevant times (collectively, the “Audit Committee
25 Defendants”). As such, they were responsible for the effectiveness of the Company’s
26 internal controls, the truth and accuracy of the Company’s financial statements, and the
27 Company’s compliance with applicable laws and regulations. During the Relevant Period,
28

1 they violated the Audit Committee Charter by engaging in or permitting the Company to
2 engage in the dissemination of materially false and misleading statements to the public and
3 to facilitate the Individual Defendants' violations of law, including breaches of fiduciary
4 duty and violations of the Exchange Act; failed to adequately exercise their risk
5 management and risk assessment functions; and failed to ensure adequate Board oversight
6 of the Company's internal control over financial reporting, disclosure controls and
7 procedures, and the Business Standards. Thus, the Audit Committee Defendants breached
8 their fiduciary duties, are not independent or disinterested, and thus demand is excused as
9 to them.

10 167. In violation of the Business Standards, the Director-Defendants conducted
11 little, if any, oversight of the Company's engagement in the Individual Defendants' scheme
12 to issue materially false and misleading statements to the public and to facilitate and
13 disguise the Individual Defendants' violations of law, including breaches of fiduciary duty,
14 unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, and
15 violations of the Exchange Act. In further violation of the Business Standards, the Director-
16 Defendants failed to comply with laws and regulations, maintain the accuracy of Company
17 records and reports, avoid conflicts of interest, conduct business in an honest and ethical
18 manner, and properly report violations of the Business Standards. Thus, the Director-
19 Defendants face a substantial likelihood of liability and demand is futile as to them.

20 168. Edwards has been and will continue to be exposed to significant losses due to
21 the wrongdoing complained of herein, yet the Directors have not filed any lawsuits against
22 themselves or any others who were responsible for that wrongful conduct to attempt to
23 recover for Edwards any part of the damages Edwards suffered and will continue to suffer
24 thereby. Thus, any demand upon the Directors would be futile.

25 169. The Director-Defendants' conduct described herein and summarized above
26 could not have been the product of legitimate business judgment as it was based on bad
27 faith and intentional, reckless, or disloyal misconduct. Thus, none of the Director-
28

1 Defendants can claim exculpation from their violations of duty pursuant to the Company's
2 charter (to the extent such a provision exists). As a majority of the Directors face a
3 substantial likelihood of liability, they are self-interested in the transactions challenged
4 herein and cannot be presumed to be capable of exercising independent and disinterested
5 judgment about whether to pursue this action on behalf of the shareholders of the Company.
6 Accordingly, demand is excused as being futile.

7 170. The acts complained of herein constitute violations of fiduciary duties owed
8 by Edwards's officers and directors, and these acts are incapable of ratification.

9 171. The Director-Defendants may also be protected against personal liability for
10 their acts of mismanagement and breaches of fiduciary duty alleged herein by directors'
11 and officers' liability insurance if they caused the Company to purchase it for their
12 protection with corporate funds, i.e., monies belonging to the stockholders of Edwards. If
13 there is a directors' and officers' liability insurance policy covering the Director-
14 Defendants, it may contain provisions that eliminate coverage for any action brought
15 directly by the Company against the Director-Defendants, known as, *inter alia*, the
16 "insured-versus-insured exclusion." As a result, if the Director-Defendants were to sue
17 themselves or certain of the officers of Edwards, there would be no directors' and officers'
18 insurance protection. Accordingly, the Director-Defendants cannot be expected to bring
19 such a suit. On the other hand, if the suit is brought derivatively, as this action is brought,
20 such insurance coverage, if such an insurance policy exists, will provide a basis for the
21 Company to effectuate a recovery. Thus, demand on the Director-Defendants is futile and,
22 therefore, excused.

23 172. If there is no directors' and officers' liability insurance, then the Director-
24 Defendants will not cause Edwards to sue the Individual Defendants named herein, since,
25 if they did, they would face a large uninsured individual liability. Accordingly, demand is
26 futile in that event, as well.

27 173. Thus, for all of the reasons set forth above, all of the Director-Defendants,
28

1 and, if not all of them, at least five of the Directors, cannot consider a demand with
2 disinterestedness and independence. Consequently, a demand upon the Board is excused
3 as futile.

4 **FIRST CLAIM**

5 **Against the Individual Defendants for Violations of Section 14(a) of the Exchange
6 Act**

7 174. Plaintiff incorporates by reference and realleges each and every allegation set
8 forth above, as though fully set forth herein.

9 175. Section 14(a) of the Exchange Act, 15 U.S.C. § 78n(a)(1), provides that “[i]t
10 shall be unlawful for any person, by use of the mails or by any means or instrumentality of
11 interstate commerce or of any facility of a national securities exchange or otherwise, in
12 contravention of such rules and regulations as the [SEC] may prescribe as necessary or
13 appropriate in the public interest or for the protection of investors, to solicit or to permit
14 the use of his name to solicit any proxy or consent or authorization in respect of any security
15 (other than an exempted security) registered pursuant to section 12 of this title [15 U.S.C.
16 § 78l].”

176. Rule 14a-9, promulgated pursuant to § 14(a) of the Exchange Act, provides
17 that no proxy statement shall contain “any statement which, at the time and in the light of
18 the circumstances under which it is made, is false or misleading with respect to any material
19 fact, or which omits to state any material fact necessary in order to make the statements
20 therein not false or misleading.” 17 C.F.R. § 240.14a-9.

21 177. Under the direction and watch of Defendants Zovighian, Gallahue, Heisz,
22 LaViolette, Loranger, Mussallem, Marsh, Sequeira, and Valeriani, the 2024 Proxy
23 Statement failed to disclose, *inter alia*, that: (1) though the Company claimed its officers
24 and directors were adhering to the Business Standards, the Individual Defendants violated
25 these policies either without waivers or without such waivers being disclosed; and (2)
26 contrary to the 2024 Proxy Statement’s descriptions of the Board’s and its committees’ risk
27 oversight functions, the Board and its committees were not adequately exercising these

1 functions and were causing or permitting the Company to issue false and misleading
2 statements.

3 178. The 2024 Proxy Statement also failed to disclose that: (1) the Individual
4 Defendants indicated they had reliable information regarding the Company's projected
5 revenue and anticipated growth; (2) in so doing, the Individual Defendants underplayed the
6 risks associated with seasonality and macroeconomic fluctuations; (3) the Individual
7 Defendants' model relied too heavily or otherwise overemphasized hospitals' desires to
8 continue utilizing TAVR over newer, more innovative therapies; (4) as a result, there was
9 a significant risk that TAVR's growth would decelerate; (5) the Individual Defendants
10 were improperly interested in increasing their future compensation by seeking shareholder
11 approval of the 2024 Amended Stock Plan; and (6) the Company lacked internal controls.
12 As a result of the foregoing, the Company's public statements were materially false and
13 misleading and/or lacked a reasonable basis at all relevant times.

14 179. In the exercise of reasonable care, Defendants Zovighian, Gallahue, Heisz,
15 LaViolette, Loranger, Mussallem, Marsh, Sequeira, and Valeriani should have known that
16 by misrepresenting or failing to disclose the foregoing material facts, the statements
17 contained in the 2024 Proxy Statement were materially false and misleading. The
18 misrepresentations and omissions were material to Plaintiff in voting on the matters set
19 forth for shareholder determination in the 2024 Proxy Statement, including but not limited
20 to, the reelection of Defendants Zovighian, Gallahue, Heisz, LaViolette, Loranger,
21 Sequeira, and Valeriani, as well as elect Defendant Davis for the first time, to the Board,
22 and the approval of the 2024 Amended Stock Plan.

23 180. As a result of the material misstatements and omissions contained in the 2024
24 Proxy Statement, Company shareholders voted, *inter alia*, to reelect Defendants Zovighian,
25 Gallahue, Heisz, LaViolette, Loranger, Sequeira, and Valeriani, as well as elect Defendant
26 Davis for the first time, to the Board, thereby allowing them to continue breaching their
27 fiduciary duties to the Company, and to approve the 2024 Amended Stock Plan.

181. The Company was damaged as a result of the Defendants Zovighian, Gallahue, Heisz, LaViolette, Loranger, Mussallem, Marsh, Sequeira, and Valeriani's material misrepresentations and omissions in the 2024 Proxy Statement.

182. Plaintiff, on behalf of Edwards, has no adequate remedy at law.

SECOND CLAIM

Against the Individual Defendants for Violations of Section 10(b) and Rule 10b-5 of the Exchange Act

183. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

184. The Individual Defendants participated in a scheme to defraud with the purpose and effect of defrauding Edwards. Not only is Edwards now defending claims that it violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, but the Company itself is also one of the largest victims of the unlawful scheme perpetrated upon Edwards by the Individual Defendants. With the price of its common stock trading at artificially inflated prices due to the Individual Defendants' misconduct, the Individual Defendants caused the Company to repurchase **2,174,656** of its own shares at artificially inflated prices, damaging Edwards.

185. During the Relevant Period, the Individual Defendants also individually and in concert, directly and indirectly, by the use and means of instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct designed to falsify the Company's press releases, public statements made in earnings calls, and periodic and current reports filed with the SEC.

186. The Individual Defendants employed devices, schemes, and artifices to defraud while in the possession of adverse, material, non-public information and engaged in acts, practices and a course of conduct that included the making of, or participation in the making of, untrue and/or misleading statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Edwards not misleading.

187. The Individual Defendants as top executives acted with scienter during the Relevant Period, in that they either had actual knowledge of the scheme and the misrepresentations and/or omissions of material facts set forth herein or acted with reckless disregard for the truth in that they failed to ascertain and to disclose the true facts, even though such facts were available to them. The Individual Defendants were the top executives of the Company, or received direct briefings from them, and were therefore directly responsible for the scheme set forth herein and for the false and misleading statements and/or omissions disseminated to the public through filings with the SEC.

188. By virtue of the foregoing, the Individual Defendants have violated §10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

THIRD CLAIM

Against the Individual Defendants for Violations of Section 20(a) of the Exchange Act

189. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

190. The Individual Defendants, by virtue of their positions with Edwards and their specific acts, were, at the time of the wrongs alleged herein, controlling persons of Edwards and each of its officers and directors who made the false and misleading statements alleged herein within the meaning of §20(a) of the Exchange Act. The Individual Defendants had the power and influence and exercised the same to cause Edwards to engage in the illegal conduct and practices complained of herein.

191. Plaintiff, on behalf of Edwards, has no adequate remedy at law.

FOURTH CLAIM

Against the Individual Defendants for Breach of Fiduciary Duties

192. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

193. Each Individual Defendant owed to the Company the duty to exercise candor, good faith, and loyalty in the management and administration of Edwards's business and

1 affairs.

2 194. Each of the Individual Defendants violated and breached their fiduciary duties
3 of candor, good faith, loyalty, reasonable inquiry, oversight, and supervision.

4 195. The Individual Defendants' conduct set forth herein was due to their
5 intentional or reckless breach of the fiduciary duties they owed to the Company, as alleged
6 herein. The Individual Defendants intentionally or recklessly breached or disregarded their
7 fiduciary duties to protect the rights and interests of Edwards.

8 196. In breach of their fiduciary duties owed to Edwards, the Individual Defendants
9 willfully or recklessly made and/or caused the Company to make false and misleading
10 statements and/or omissions of material fact that failed to disclose, *inter alia*, that: (1) the
11 Individual Defendants indicated they had reliable information regarding the Company's
12 projected revenue and anticipated growth; (2) in so doing, the Individual Defendants
13 underplayed the risks associated with seasonality and macroeconomic fluctuations; (3) the
14 Individual Defendants' model relied too heavily or otherwise overemphasized hospitals'
15 desires to continue utilizing TAVR over newer, more innovative therapies; (4) as a result,
16 there was a significant risk that TAVR's growth would decelerate; (5) the Individual
17 Defendants were improperly interested in increasing their future compensation by seeking
18 shareholder approval of the 2024 Amended Stock Plan; and (6) the Company lacked
19 internal controls. As a result of the foregoing, the Company's public statements were
20 materially false and misleading and/or lacked a reasonable basis at all relevant times.

21 197. In further breach of their fiduciary duties, the Individual Defendants failed to
22 correct and/or caused the Company to fail to correct the false and misleading statements
23 and/or omissions of material fact referenced herein, which renders them personally liable
24 to the Company for breaching their fiduciary duties.

25 198. Also, in breach of their fiduciary duties, the Individual Defendants caused the
26 Company to fail to maintain internal controls.

27 199. In yet further breach of their fiduciary duties, during the Relevant Period, the
28

1 Individual Defendants willfully or recklessly caused the Company to repurchase millions
2 of shares of its own common stock at artificially inflated prices before the fraud was
3 exposed, while five of the Individual Defendants engaged in lucrative insider sales, netting
4 proceeds of approximately \$12.3 million.

5 200. The Individual Defendants had actual or constructive knowledge that the
6 Company issued materially false and misleading statements, and they failed to correct the
7 Company's public statements and representations. The Individual Defendants had actual
8 knowledge of the misrepresentations and omissions of material facts set forth herein, or
9 acted with reckless disregard for the truth, in that they failed to ascertain and to disclose
10 such facts, even though such facts were available to them. Such material misrepresentations
11 and omissions were committed knowingly or recklessly and for the purpose and effect of
12 artificially inflating the price of Edwards's securities.

13 201. The Individual Defendants had actual or constructive knowledge that they had
14 caused the Company to improperly engage in the fraudulent scheme set forth herein and to
15 fail to maintain internal controls. The Individual Defendants had actual knowledge that the
16 Company was engaging in the fraudulent scheme set forth herein, and that internal controls
17 were not adequately maintained, or acted with reckless disregard for the truth, in that they
18 caused the Company to improperly engage in the fraudulent scheme and to fail to maintain
19 adequate internal controls, even though such facts were available to them. Such improper
20 conduct was committed knowingly or recklessly and for the purpose and effect of
21 artificially inflating the price of Edwards's securities. The Individual Defendants, in good
22 faith, should have taken appropriate action to correct the scheme alleged herein and to
23 prevent it from continuing to occur.

24 202. These actions were not a good-faith exercise of prudent business judgment to
25 protect and promote the Company's corporate interests.

26 203. As a direct and proximate result of the Individual Defendants' breaches of
27 their fiduciary obligations, Edwards has sustained and continues to sustain significant

1 damages. As a result of the misconduct alleged herein, the Individual Defendants are liable
2 to the Company.

3 204. Plaintiff, on behalf of Edwards, has no adequate remedy at law.

4 **FIFTH CLAIM**
5 **Against the Individual Defendants for Unjust Enrichment**

6 205. Plaintiff incorporates by reference and realleges each and every allegation set
7 forth above, as though fully set forth herein.

8 206. By their wrongful acts, violations of law, and false and misleading statements
9 and omissions of material fact that they made and/or caused to be made, the Individual
10 Defendants were unjustly enriched at the expense of, and to the detriment of, Edwards.

11 207. The Individual Defendants either benefitted financially from the improper
12 conduct, or received bonuses, stock options, or similar compensation from Edwards that
13 was tied to the performance or artificially inflated valuation of Edwards, or received
14 compensation or other payments that were unjust in light of the Individual Defendants' bad
15 faith conduct. This includes lavish compensation, benefits, and other payments provided
16 to the Individual Defendants who breached their fiduciary duties to the Company.

17 208. Plaintiff, as a shareholder and a representative of Edwards, seeks restitution
18 from the Individual Defendants and seeks an order from this Court disgorging all profits,
19 including from insider transactions, the redemption of preferred stock, benefits, and other
20 compensation, including any performance-based or valuation-based compensation,
21 obtained by the Individual Defendants due to their wrongful conduct and breach of their
22 fiduciary and contractual duties.

23 209. Plaintiff, on behalf of Edwards, has no adequate remedy at law.

24 **SIXTH CLAIM**
25 **Against the Individual Defendants for Abuse of Control**

26 210. Plaintiff incorporates by reference and realleges each and every allegation set
27 forth above, as though fully set forth herein.

211. The Individual Defendants' misconduct alleged herein constituted an abuse of their ability to control and influence Edwards, for which they are legally responsible.

212. As a direct and proximate result of the Individual Defendants' abuse of control, Edwards has sustained significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

213. Plaintiff, on behalf of Edwards, has no adequate remedy at law.

SEVENTH CLAIM

214. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

215. By their actions alleged herein, the Individual Defendants, either directly or through aiding and abetting, abandoned and abdicated their responsibilities and fiduciary duties with regard to prudently managing the assets and business of Edwards in a manner consistent with the operations of a publicly held corporation.

216. As a direct and proximate result of the Individual Defendants' gross mismanagement and breaches of duty alleged herein, Edwards has sustained and will continue to sustain significant damages.

217. As a result of the misconduct and breaches of duty alleged herein, the Individual Defendants are liable to the Company.

218. Plaintiff, on behalf of Edwards, has no adequate remedy at law.

EIGHTH CLAIM

Against Individual Defendants for Waste of Corporate Assets

219. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

220. The Individual Defendants caused the Company to pay the Individual Defendants excessive salaries and fees, to the detriment of the shareholders and the Company.

221. As a result of the foregoing, and by failing to properly consider the interests of the Company and its public shareholders, the Individual Defendants have caused Edwards to waste valuable corporate assets, to incur many millions of dollars of legal liability and/or costs to defend unlawful actions, to engage in internal investigations, and to lose financing from investors and business from future customers who no longer trust the Company and its products.

222. In addition, the Individual Defendants caused the Company to repurchase shares of its own common stock at artificially inflated prices, thereby wasting the Company's assets.

223. As a result of the waste of corporate assets, the Individual Defendants are each liable to the Company.

224. Plaintiff, on behalf of Edwards, has no adequate remedy at law.

NINTH CLAIM

Against Defendants Zovighian, Wood, and Ullem for Contribution Under Sections 10(b) and 21D of the Exchange Act

225. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

226. Edwards, Defendant Zovighian, Defendant Wood, and Defendant Ullem are named as defendants in the Securities Class Action, which asserts claims under the federal securities laws for violations of Sections 10(b) and 20(a) of the Exchange Act, and SEC Rule 10b-5 promulgated thereunder. If and when the Company is found liable in the Securities Class Action for these violations of the federal securities laws, the Company's liability will be in whole or in part due to Defendant Zovighian's, Defendant Wood's, and Defendant Ullem's willful and/or reckless violations of their obligations as officers and/or directors of Edwards.

227. Defendants Zovighian, Wood, and Ullem, because of their positions of control and authority as CEO, Corporate Vice President and Group President of TAVR and Surgical Structural Heart Therapies, and Corporate Vice President and CFO of Edwards,

1 respectively, were able to and did, directly and/or indirectly, exercise control over the
2 business and corporate affairs of Edwards, including the wrongful acts complained of
3 herein and in the Securities Class Action.

4 228. Accordingly, Defendants Zovighian, Wood, and Ullem are liable under 15
5 U.S.C. § 78j(b), which creates a private right of action for contribution, and Section 21D
6 of the Exchange Act, 15 U.S.C. § 78u-4(f), which governs the application of a private right
7 of action for contribution arising out of violations of the Exchange Act.

8 229. As such, Edwards is entitled to receive all appropriate contribution or
9 indemnification from Defendants Zovighian, Wood, and Ullem.

10 **PRAYER FOR RELIEF**

11 FOR THESE REASONS, Plaintiff demands judgment in the Company's favor
12 against all Individual Defendants as follows:

13 (a) Declaring that Plaintiff may maintain this action on behalf of Edwards,
14 and that Plaintiff is an adequate representative of the Company;

15 (b) Declaring that the Individual Defendants have breached and/or aided
16 and abetted the breach of their fiduciary duties to Edwards;

17 (c) Determining and awarding to Edwards the damages sustained by it as a
18 result of the violations set forth above from each of the Individual Defendants, jointly and
19 severally, together with pre-judgment and post-judgment interest thereon;

20 (d) Directing Edwards and the Individual Defendants to take all necessary
21 actions to reform and improve Edwards's corporate governance and internal procedures to
22 comply with applicable laws and to protect Edwards and its shareholders from a repeat of
23 the damaging events described herein, including, but not limited to, putting forward for
24 shareholder vote the following resolutions for amendments to the Company's Bylaws
25 and/or Certificate of Incorporation and the following actions as may be necessary to ensure
26 proper corporate governance policies:

27 1. a proposal to strengthen the Board's supervision of operations and

1 develop and implement procedures for greater shareholder input into the policies
2 and guidelines of the board;

3 2. a provision to permit the shareholders of Edwards to nominate at least
4 five candidates for election to the Board;

5 3. a proposal to ensure the establishment of effective oversight of
6 compliance with applicable laws, rules, and regulations;

7 (e) Awarding Edwards restitution from Individual Defendants, and each of
8 them;

9 (f) Awarding Plaintiff the costs and disbursements of this action, including
10 reasonable attorneys' and experts' fees, costs, and expenses; and

11 (g) Granting such other and further relief as the Court may deem just and
12 proper.

13 **JURY TRIAL DEMANDED**

14 Plaintiff hereby demands a trial by jury.

16 Dated: December 31, 2024

17 Respectfully submitted,

18 **THE BROWN LAW FIRM, P.C.**

19 /s/ Robert C. Moest

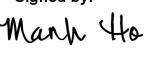
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26
27
28 *Counsel for Plaintiff*

VERIFICATION

I, Manh Ho, am a plaintiff in the within action. I have reviewed the allegations made in this Shareholder Derivative Complaint, know the contents thereof, and authorize its filing. To those allegations of which I have personal knowledge, I believe those allegations to be true. As to those allegations of which I do not have personal knowledge, I rely upon my counsel and their investigation and believe them to be true.

I declare under penalty of perjury that the foregoing is true and correct. Executed this
31 day of December, 2024.

Signed by:

Manh Ho
3ED253794508459...
Manh Ho